HBsAg Rapid Test Cassette (Whole Blood/Serum/Plasma) Package Insert

REF IHBSG-402	English

A rapid test for the qualitative detection of Hepatitis B Surface Antigen (HBsAg) in human whole blood, serum or plasma.
For laboratory professional in vitro diagnostic use only.

【INTENTED USE】

The HBsAg Rapid Test Cassette is a rapid chromatographic immunoassay for the qualitative detection of Hepatitis B Surface Antigen in human whole blood, serum or plasma to aid in the diagnosis of HBsAg infection.

The product is intended to be used by trained laboratory personnel. For laboratory use only.

The test provides preliminary test results. Negative results will not preclude Hepatitis B virus infection and they can't be used as the sole basis for treatment or other management decision. Not for Self-testing use. Not for near-patient use. Not for blood donor screening.

【SUMMARY】

Viral hepatitis is a systemic disease primarily involving the liver. Most cases of acute viral hepatitis are caused by Hepatitis A virus, Hepatitis B virus (HBV) or Hepatitis C virus. The complex antigen found on the surface of HBV is called HBsAg. Previous designations included the Australia or Au antigen. In a typical Hepatitis B infection, Chronic HBV infection is defined as either the presence of HBsAg in the serum for at least 6 months or the presence of HBsAg in a person who tests negative for immunoglobulin M antibodies to hepatitis B core antigen. Unlike persons who recover from acute HBV infection, persons with chronic HBV infection do not develop anti-HBs, and HBsAg typically persists for decades.[1] The presence of HBsAg in serum indicates that the patient has contracted HBV infection.[2] HBsAg has four principal subtypes: adw, ayw, adr and ayr. Because of antigenic heterogeneity of the determinant, there are 10 major serotypes of Hepatitis B virus.

The HBsAg Rapid Test Cassette is a rapid test to qualitatively detect the presence of HBsAg in whole blood, serum or plasma specimen. The test utilizes a combination of monoclonal and monoclonal antibodies to selectively detect elevated levels of HBsAg in whole blood, serum or plasma.

【PRINCIPLE】

The HBsAg Rapid Test Cassette is a qualitative, solid phase, two-site sandwich immunoassay for the detection of HBsAg in whole blood, serum or plasma. The membrane is pre-coated with anti-HBsAg antibodies on the test line region of the test. During testing, the whole blood, serum or plasma specimen reacts with the particle coated with anti-HBsAg antibodies to form a complex. The complex migrates upward on the membrane chromatographically by capillary action to react with anti-HBsAg antibodies on the membrane and generate a colored line. The presence of this colored line in the test region indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a colored line will always appear in the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

【REAGENTS】

The test contains anti-HBsAg particles and anti-HBsAg coated on the membrane.

【WARNINGS AND PRECAUTIONS】

Please read all the information in this package insert before performing the test.

•For laboratory professional use only. For *in vitro* diagnostic use only.
•Do not use after expiration date. Do not reuse the test.
•The test should remain in the sealed pouch until use. Do not use test if the pouch is damaged.
•Do not eat, drink or smoke in the area where the specimens or kits are handled.
•Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout all procedures and follow the standard procedures for proper disposal of specimens.
•Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
•The used test should be discarded according to local regulations.
•Humidity and temperature may adversely affect results.
•Wash hands thoroughly before and after handling.
•Any serious incident that has occurred in relation to the test shall be reported to the manufacturer and the competent authority.
•Components provided in the kit are approved for use in the HBsAg Rapid Test Cassette. Do not use any other commercial kit component.

【STORAGE AND STABILITY】

The kit can be stored at room temperature or refrigerated (2-30 ℃). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. **DO NOT FREEZE**. Do not use beyond the expiration date.

Note: It is suggested to use test within one hour after removing it from the foil pouch.

【SPECIMEN COLLECTION AND PREPARATION】

- The HBsAg Rapid Test Cassette can be performed using whole blood (from venipuncture), serum or plasma.

- **Venous whole blood:**
  Collect whole blood specimen into a collection tube (with specified anticoagulant, namely EDTA K2, heparin sodium, sodium citrate or potassium oxalate) according to standard venous blood sampling process. Other anticoagulants may lead to incorrect results. Whole blood specimen can be stored at 2-8°C for up to 2 days if it is not used immediately after being sampled. Do not freeze whole blood specimen. Before testing, gently shake the blood tube to obtain a homogeneous specimen.

- **Serum:**
  Collect whole blood specimen into a collection tube without anticoagulant according to standard venous blood sampling process. Leave to settle for 30 minutes for blood coagulation, and then spin at 1,000 to 1,200 g for 10 to 15 minutes at room temperature to obtain the serum supernatant. Don't leave samples in centrifuge after spinning.

- **Plasma:**
  Collect whole blood specimen into a collection tube (with specified anticoagulant, namely EDTA K2, heparin sodium, citrate sodium or potassium oxalate) according to standard venous blood sampling process. Gently invert the collection tube for several times and leave to settle for 30 minutes for blood coagulation, and then spin at 1,000 to 1,200 g for 10 to 15 minutes at room temperature to obtain the plasma supernatant. Don't leave samples in centrifuge after spinning.

- Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.
- Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 3 days, for long term storage, specimens should be kept below -20°C. Whole blood collected by venipuncture should be stored at 2 – 8 °C if the test is to be run within 2 days of collection. Do not freeze whole blood specimens.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
- If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.

【MATERIALS】

Materials provided

	Kit size	40T/kits	25T/kits
Components	Tests	40	25
	Package insert	1	1
	Droppers	40	25
	Buffer 3mL (PBS, 0.02% Proclin 300, ≤0.02% NaN_3)	2	1

Materials required but not provided

• Specimen collection containers • Centrifuge • Timer

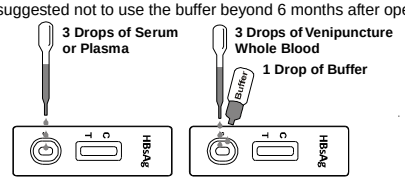
【DIRECTIONS FOR USE】

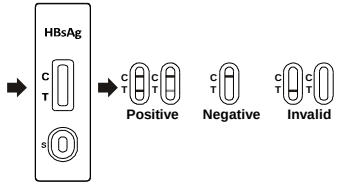
Allow the test, specimen and buffer to reach room temperature (15-30°C) prior to testing.

1. Bring the pouch to room temperature before opening it. Remove the test cassette from the sealed pouch and use it as soon as possible.
2. Place the cassette on a clean and level surface.
   For **Serum or Plasma** specimen:
   - Hold the dropper vertically and transfer **3 drops of serum or plasma** to the specimen well (S) of test cassette and start the timer. See illustration below.

   For **Venous Whole Blood** specimen:
   - Hold the dropper vertically and transfer **3 drops of whole blood** to the specimen well (S) of test cassette, then **add 1 drop of buffer**, and start the timer. See illustration below.
3. Wait for the colored line(s) to appear. **Read results at 15~30 minutes.** Do not interpret the result after 30 minutes.

Note: It is suggested not to use the buffer beyond 6 months after opening the vial.





【INTERPRETATION OF RESULTS】

(Please refer to the illustration above)

POSITIVE:* Two colored lines appear. One colored line should be in the control region (C) and another colored line should be in the test region (T).

***NOTE**: The intensity of the color in the test line region (T) will vary depending on the concentration of HBsAg present in the specimen. Therefore, any shade of color in the test region (T) should be considered positive.

NEGATIVE: One colored line appears in the control region (C). No colored line appears in the test region (T).

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact local distributor.

【QUALITY CONTROL】

A procedural control is included in the test. A colored line appearing in the control line region(C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

【LIMITATIONS】

1. The HBsAg Rapid Test Cassette is for professional *in vitro* diagnostic use only. The test should be used for the detection of HBsAg in human whole blood, serum or plasma specimen. Neither the quantitative value nor the rate of HBsAg concentration can be determined by this qualitative test.
2. The HBsAg Rapid Test Cassette will only indicate the presence of HBsAg in the specimen and should not be used as the sole criteria for the diagnosis of Hepatitis B viral infection.
3. Other forms of infection like seronegative infection in window period and occult hepatitis B infection could be missed by HBsAg assays.
4. When the test results and clinical symptoms are inconsistent, it should be confirmed by ELISA, CMIA or NAT.
5. The HBsAg Rapid Test Cassette cannot detect less than 1 ng/mL of HBsAg in specimens. If the test result is negative and clinical symptoms persist, additional follow-up testing using other clinical methods is suggested. A negative result at any time does not preclude the possibility of Hepatitis B infection.
6. The hematocrit of the whole blood should be between 25% and 65%.

【PERFORMANCE CHARACTERISTICS】

Sensitivity and Specificity

The HBsAg Rapid Test Cassette (Whole Blood/Serum/Plasma) was tested serum, plasma and whole blood clinical specimens and compared with CE marked CMIA test .The results show that the relative sensitivity of the HBsAg Rapid Test Cassette (Whole Blood/Serum/Plasma) is 99.9% and the relative specificity is 99.9%.

For Whole Blood/Serum/Plasma Specimen

Sample Status	Sample HBsAg Status	Comparator Method	Serum/Plasma Specimen			Whole Blood Specimen		
			Specimen Number	HBsAg Rapid Test		Specimen Number	HBsAg Rapid Test	
				Positive	Negative		Positive	Negative
HBsAg positive sample	Positive	CMIA	722	721	1	50	50	0
Blood Donation	Negative	CMIA	900	2	898	200	0	200
Clinical (hospital) sample	Negative	CMIA	1282	2	1280	30	0	30
Pregnant Woman	Negative	CMIA	215	0	215	/	/	/
Interference Substance	Negative	CMIA	140	0	140	/	/	/

Relative Sensitivity =99.87%(95%CI*:99.28%->99.99%)
Relative Specificity =99.86% (95%CI*:99. 63%-99.96%)
Overall Accuracy=99.86% (95% CI*: 99.67%-99.95%) *Confidence Intervals

Separately for Serum Specimen

Sample Status	Sample HBsAg Status	Comparator Method	Serum Specimen		
			Specimen Number	HBsAg Rapid Test	
				Positive	Negative
HBsAg positive sample	Positive	CMIA	492	492	0
Blood Donation	Negative	CMIA	800	2	798
Clinical (hospital) sample	Negative	CMIA	1062	2	1060
Pregnant Woman	Negative	CMIA	215	0	215
Interference Substance	Negative	CMIA	140	0	140

Relative Sensitivity =>99.99%(95%CI*:99.25%->99.99%)
Relative Specificity =99.82% (95%CI*:99.54%-99.95%)
Overall Accuracy=99.85% (95% CI*: 99.62%-99.96%) *Confidence Intervals

Separately for Plasma Specimen

Sample Status	Sample HBsAg Status	Comparator Method	Plasma Specimen		
			Specimen Number	HBsAg Rapid Test	
				Positive	Negative
HBsAg positive sample	Positive	CMIA	230	229	1
Blood Donation	Negative	CMIA	100	0	100
Clinical (hospital) sample	Negative	CMIA	220	0	220
Pregnant Woman	Negative	CMIA	/	/	/
Interference Substance	Negative	CMIA	/	/	/

Relative Sensitivity =99.57%(95%CI*:97.60%-99.99%)
Relative Specificity =>99.99% (95%CI*:98.85%->99.99%)
Overall Accuracy=99.82% (95% CI*: 98.99%->99.99%) *Confidence Intervals

Separately for Whole Blood Specimen

Sample Status	Sample HBsAg Status	Comparator Method	Whole Blood Specimen		
			Specimen Number	HBsAg Rapid Test	
				Positive	Negative
HBsAg positive sample	Positive	CMIA	50	50	0
Blood Donation	Negative	CMIA	200	0	200
Clinical (hospital) sample	Negative	CMIA	30	0	30
Pregnant Woman	Negative	CMIA	/	/	/
Interference Substance	Negative	CMIA	/	/	/

Relative Sensitivity =>99.99%(95%CI*:92.89%->99.99%)
Relative Specificity =>99.99% (95%CI*:98.41%->99.99%)
Overall Accuracy=>99.99% (95% CI*: 98.69%->99.99%) *Confidence Intervals

Serum vs. Plasma

Sensitivity in seropositive paired serum and plasma specimens:

A total of 100 seropositive paired serum and plasma were tested with HBsAg Rapid Test Cassette, respectively. There was a good correlation of testing results between serum and plasma with HBsAg seropositive samples.

Specimen Type	Number of specimens tested	Agreement for positive results by HBsAg Rapid Test
Serum	100	>99.9%(100/100)
Plasma	100	>99.9%(100/100)

Specificity in seropositive paired serum and plasma specimens:

A total of 220 seronegative paired serum and plasma were tested with HBsAg Rapid Test Cassette, respectively. There was a good correlation of testing results between serum and plasma with HBsAg seronegative samples.

Specimen Type	Number of specimens tested	Agreement for negative results by HBsAg Rapid Test
Serum	220	>99.9%(220/220)
Plasma	220	>99.9%(220/220)

Sero-conversion panels

30 sero-conversion panels were studied with HBsAg Rapid Test Cassette (Whole Blood/ Serum/Plasma) and compared to results from CE marked Turklab HBsAg test as reference assay. HBsAg Rapid Test Cassette (Whole Blood/Serum/Plasma) has the similar detection capacity as reference assay.

Hook Effect

There is no dose hook effect with the test, when the HBsAg level is no more than 500 ng/mL.

Intra-Assay

Within-run precision has been determined by using four specimens: 0ng/mL, 1ng/mL, 7ng/mL and 20ng/mL positive specimens. The study was performed 15 replicates per day for 5 consecutive days by one operator using 1 lot of HBsAg Rapid Test, 1 lot of buffer. No difference was detected in intra lot.

Inter-Assay

Between-run precision has been determined by using four specimens: 0ng/mL, 1ng/mL, 7ng/mL and 20ng/mL positive specimens. The study was performed 15 replicates per day for 5 consecutive days in 3 different sites using 3 separate lots of HBsAg Rapid Test (one lot per site), and three operators per site. No difference was detected between days, sites, lots and operators.

Cross-reactivity

The HBsAg Rapid Test Cassette has been tested for anti-HCV, anti-HEV, anti-Syphilis, anti-EBV, CEA, AFP, PSA, CA15-3, CA19-9, CA125, anti-HAV IgM, anti-HIV, anti-RF, anti-H.pylori, anti-CMV IgG, anti-Rubella IgG, anti-TOXO IgG, anti-HSV 1 IgG, anti-HSV 2 IgG, Dengue NS1 and Zika NS1 positive specimens. The results showed no cross-reactivity.

Interfering Substances

The following potentially interfering substances were added to HBsAg negative and positive specimens. None of the substances at the concentration tested interfered in the assay.

Acetaminophen: 20 mg/dL	Caffeine: 20 mg/dL
Acetylsalicylic Acid: 20 mg/dL	Gentisic Acid: 20 mg/dL
Ascorbic Acid: 1g/dL	Albumin: 2 g/dL
Creatin: 200 mg/dL	Hemoglobin:2000mg/dL
Bilirubin: 0.5g/dL	Oxalic Acid: 60mg/dL
Cocaine: 20mg/dL	Methadone: 20mg/dL

【BIBLIOGRAPHY】

1. Colin W. Shepard, Edgar P. Simard, Lyn Finelli, Anthony E. Fiore, Beth P. Bell, Hepatitis B Virus Infection: Epidemiology and Vaccination, Epidemiologic Reviews, Volume 28, Issue 1, August 2006, Pages 112–125.
2. Ravi Kaul,Chapter 9.17 - Hepatitis, Editor(s): David Wild, The Immunoassay Handbook(Fourth Edition),Elsevier,2013,Pages 901-911.

Index of Symbols

	Consult instructions for use or consult electronic instructions for use		Contains sufficient for <n> tests		Temperature limit
IVD	*In vitro* diagnostic medical device	LOT	Batch code	REF	Catalogue number
EC REP	Authorized representative in the European Community		Use-by date		Do not re-use
	Do not use if package is damaged and consult instructions for use		Manufacturer		Caution

Hangzhou AllTest Biotech Co.,Ltd.
#550,Yinhai Street
Hangzhou Economic & Technological Development Area
Hangzhou, 310018 P.R. China
Web: www.alltests.com.cn Email: info@alltests.com.cn

CE 2934

EC REP
MedNet EC-REP GmbH
Borkstrasse 10,
48163 Muenster,
Germany

Number: 146262000
Effective date: 2022-05-11

HBsAg greito testo kasetė (Bendras kraujas / serumas / plazma) Pakuotės aprašymas

REF IHBSG-402 | **Lietuvių k.**

Greitasis testas hepatito B paviršiaus antigenų (HBsAg) kokybiniam nustatymui žmogaus bendrame kraujyje, serume arba plazmoje.
Tik profesionaliam in vitro diagnostiniam naudojimui laboratorijoje.

【PASKIRTIS】

HBsAg greitojo testo kasetė yra greitas chromatografinis imunologinis tyrimas, skirtas kokybiškai nustatyti hepatito B paviršiaus antigeną žmogaus bendrame kraujyje, serume arba plazmoje, siekiant padėti diagnozuoti HBsAg infekciją.
Produktą gali naudoti tik apmokytas laboratorijos personalas. Tik laboratoriniam naudojimui.
Testas pateikia preliminarius rezultatus. Neigiami rezultatai neatmeta hepatito B viruso infekcijos buvimo galimybės ir jie negali būti vienintelis gydymo ar kitokių su pacientu susijusių sprendimų pagrindas.
Neskirta saveș patikrai. Neskirta naudoti šalia paciento. Neskirta kraujo donorų skryningui.

【SANTRAUKA】

Virusinis hepatitas yra sisteminė liga, pirmiausia apimanti kepenis. Daugumą ūminio virusinio hepatito atvejų sukelia hepatito A virusas, hepatito B virusas (HBV) arba hepatito C virusas. HBV paviršiuje esantis kompleksinis antigenas vadinamas HBsAg. Ankstesni pavadinimai buvo Australijos arba Au antigenas. Lėtinė HBV infekcija apibrėžiama kaip HBsAg buvimas serume bent 6 mėnesius arba HBsAg buvimas asmeniui, kurio hepatito B šerdies antigeno imunoglobulino M antikūnų tyrimas yra neigiamas. Kitaip nei asmenims, pasveikusiems po ūmios HBV infekcijos, asmenims, sergantiems lėtine HBV infekcija, neišsivysto anti-HBs, o HBsAg paprastai išlieka dešimtmečius.[1] HBsAg buvimas serume rodo, kad pacientas yra užsikrėtęs HBV infekcija.[2] HBsAg turi keturis pagrindinius potipius: adw, ayw, adr ir ayr. Dėl antigeninio determinanto heterogeniškumo yra 10 pagrindinių hepatito B viruso serotipų.
HBsAg greitojo testo kasetė yra greitasis testas, kuriuo kokybiškai nustatomas HBsAg buvimas bendrame kraujyje, serume arba plazmoje. Tyrime naudojamas monokloninių ir monokloninių antikūnų derinys, kuriuo selektyviai nustatomas padidėjęs HBsAg kiekis bendrame kraujyje, serume arba plazmoje.

【PRINCIPAS】

HBsAg greitojo testo kasetė yra kokybinis kietosios fazės, dviejų vietų daugiasluoksnis imunofermentinis testas, skirtas HBsAg aptikti bendrame kraujyje, serume arba plazmoje. Membrana yra padengta anti-HBsAg antikūnais testo linijos srityje. Tyrimo metu bendro kraujo, serumo ar plazmos mėginys reaguoja su anti-HBsAg antikūnais padengtomis dalelėmis ir suformuoja kompleksą. Membranoje mišinys kapiliariniu būdu chromatografiškai migruoja aukštyn ir reaguoja su anti-HBsAg antikūnais membranoje ir sugeneruoja spalvotą liniją. Šios spalvotos linijos buvimas testo laukelyje rodo teigiamą rezultatą, o jos nebuvimas - neigiamą rezultatą. Kontrolinės linijos srityje visada atsiranda spalvota linija, rodanti, kad buvo naudotas reikiamas mėginio kiekis ir mėginys tinkamai padengė membraną.

【REAGENTAI】

Tyrime yra anti-HBsAg dalelių ir anti-HBsAg, padengtų ant membranos.

ĮSPĖJIMAI IR ATSARGUMO PRIEMONĖS

Prieš atlikdami tyrimą perskaitykite visą šiame pakuotės lapelyje pateiktą informaciją.

•Tik profesionaliam naudojimui laboratorijoje. *Tik in vitro* diagnostiniam naudojimui.
•Nenaudokite pasibaigus galiojimo datai. Testo nenaudokite pakartotinai.
•Iki naudojimo testo kasetė turi būti originalioje sandarioje pakuotėje. Nenaudokite, jei pakuotė pažeista.
•Nevalgykite, negerkite ir nerūkykite mėginių ar rinkinių tvarkymo vietoje.
•Su visais mėginiais elkitės kaip su potencialiai infekcinėmis medžiagomis. Visos procedūros metu laikykitės nustatytų atsargumo priemonių dėl mikrobiologinio pavojaus ir laikykitės standartinių tinkamo mėginių utilizavimo procedūrų.
•Mėginių tyrimo metu dėvėkite apsauginius drabužius, pvz., laboratorinius chalatus, vienkartines pirštines ir akių apsaugos priemones.
•Atliekos turi būti išmetamos laikantis vietinių taisyklių.
•Drėgmė ir temperatūra gali turėti neigiamos įtakos rezultatams.
•Po naudojimo gerai nusiplaukite rankas.
•Apie visus su tyrimu susijusius rimtus incidentus būtina pranešti gamintojui ir kompetentingai institucijai.
•Rinkinyje pateikti komponentai yra patvirtinti naudoti HBsAg greitojo testo kasetėje. Nenaudokite jokio kito komercinio rinkinio komponento.

【LAIKYMAS IR STABILUMAS】

Rinkinį galima laikyti kambario temperatūroje arba šaldytuve (2-30 °C). Testo kasetė išlieka stabili iki ant pakuotės nurodytos galiojimo pabaigos datos. Iki naudojimo testo kasetė turi būti originalioje sandarioje pakuotėje. **NEUŽŠALDYKITE.** Nenaudokite pasibaigus galiojimo laikui.
Pastaba. Rekomenduojama testą panaudoti per vieną valandą nuo jo išėmimo iš folijos maišelio. **【MĖGINIŲ PAĖMIMAS IR PARUOŠIMAS】**

- HBsAg greitojo testo kasetė gali būti naudojama su bendro kraujo (paimto iš venos), serumo ar plazmos mėginiais.

- **Veninis kraujas:**
  Surinkite bendro kraujo mėginį į mėgintuvėlį (su nurodytu antikoaguliantu, t. y. EDTA K2, heparino natrio druska, natrio citratu arba kalio oksalatu) pagal standartinę veninio kraujo paėmimo procedūrą. Kiti antikoaguliantai gali lemti klaidingus rezultatus. Jei bendro kraujo mėginys nenaudojamas iš karto po mėginio paėmimo, laikykite jį iki 2 dienų 2-8 °C temperatūroje. Neužšaldykite bendro kraujo mėginio. Prieš tyrimą švelniai pakratykite mėgintuvėlį, kad mėginys homogenizuotųsi.

- **Serumas:**
  Surinkite bendro kraujo mėginį į mėgintuvėlį be antikoaguianto pagal standartinę veninio kraujo paėmimo procedūrą. Palikite nusistovėti 30 minučių, kad kraujas koaguliuotų, tada bent 15 minučių centrifuguokite 1,000-1,200 sūkių per minutę greičiu, kad gautumėte serumo supernatantą. Po centrifugavimo, mėginių nepalikite centrifugoje.

- **Plazma:**
  Surinkite bendro kraujo mėginį į mėgintuvėlį (su nurodytu antikoaguliantu, t. y. EDTA K2, heparino natrio druska, natrio citratu arba kalio oksalatu) pagal standartinę veninio kraujo paėmimo procedūrą. Palikite nusistovėti 30 minučių, kad kraujas koaguliuotų, tada bent 15 minučių centrifuguokite 1,000-1,200 sūkių per minutę greičiu, kad gautumėte serumo supernatantą. Po centrifugavimo, mėginių nepalikite centrifugoje.

- Kad išvengtumėte hemolizės, kuo greičiau atskirkite serumą ar plazmą nuo kraujo. Galima naudoti tik skaidrius, ne hemolizuotus mėginius.
- Tyrimas turėtų būti atliekamas iš karto po mėginio paėmimo. Nepalikite mėginių kambario temperatūroje ilgesnį laiką. Serumo ir plazmos mėginiai gali būti laikomi 2-8 °C temperatūroje ne ilgiau kaip 3 dienas, jei mėginiai laikomi ilgai, juos reikia laikyti žemesnėje nei -20 °C temperatūroje. Venos punkcijos būdu paimtą bendrą kraują reikia laikyti 2-8 °C temperatūroje, jei tyrimas turi būti atliktas per 2 dienas nuo paėmimo. Neužšaldykite bendro kraujo mėginio.
- Prieš tyrimą mėginiai turi būti kambario temperatūros. Užšaldyti mėginiai prieš tyrimą turi būti pilnai atšildyti ir gerai išmaišyti. Mėginių negalima pakartotinai užšaldyti ir atšildyti.
- Jei mėginiai turi būti transportuojami, jie turi būti supakuoti laikantis vietos taisyklių dėl etiologinių agentų transportavimo.

【MEDŽIAGOS 】

Tiekiamos medžiagos

	Rinkinio dydis	40 testų rinkinyje	25 testai rinkinyje
Komponentai	**Testai**	40	25
	Pakuotės aprašymas	1	1
	Lašintuvai	40	25
	Buferis 3ml (PBS, 0,02% Proclin 300, ≤0,02% NaN_3)	2	1

Reikalingos netiekiamos medžiagos

• Mėginių paėmimo konteineriai • Centrifuga • Laikmatis

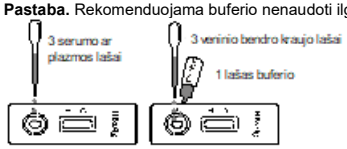
【NAUDOJIMO INSTRUKCIJOS】

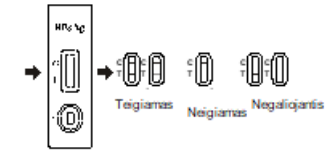
Prieš tyrimą, testas, mėginys ir buferis turi pasiekti kambario temperatūrą (15-30°C).

1. Prieš atidarant, pakuotė turi būti kambario temperatūros. Išimkite testo kasetę iš pakuotės ir kuo greičiau ją panaudokite.
2. Padėkite kasetę ant švaraus ir lygaus paviršiaus.
   Serumo ar plazmos mėginiai:
   - Lašintuvą laikydami vertikaliai **įlašinkite 3 serumo ar plazmos lašus** į mėginio šulinėlį (S) ir įjunkite laikmatį. Žr. iliustraciją žemiau.

   Veninio kraujo mėginiai:
   - Lašintuvą laikydami vertikaliai **įlašinkite 3 bendro kraujo lašus** į mėginio šulinėlį (S), **įlašinkite 1 lašą buferio** ir įjunkite laikmatį. Žr. iliustraciją žemiau.
3. Palaukite, kol atsiras spalvota linija (-os). **Rezultatus nuskaitykite po 15~30 minučių.** Po 30 minučių rezultato neinterpretuokite.

Pastaba. Rekomenduojama buferio nenaudoti ilgiau kaip 6 mėnesius po buteliuko atidarymo.





【REZULTATŲ INTERPRETAVIMAS】

(Žr. iliustraciją aukščiau)

TEIGIAMAS: *atsiranda dvi spalvotos linijos. Viena spalvota linija turėtų būti kontrolinėje srityje (C), o kita spalvota linija - tyrimo srityje (T).
***PASTABA.** Spalvos intensyvumas tyrimo linijos srityje (T) priklauso nuo HBsAg koncentracijos mėginyje. Todėl bet koks spalvos atspalvis tyrimo srityje (T) turėtų būti laikomas teigiamu.
NEIGIAMAS: Kontrolinėje srityje (C) atsiranda viena spalvota linija. Tyrimo srityje (T) spalvota linija neatsiranda.
NEGALIOJANTIS: Kontrolinė linija neatsiranda. Nepakankamas mėginio tūris arba netinkami procedūriniai metodai yra labiausiai tikėtinos kontrolinės linijos neatsiradimo priežastys. Peržiūrėkite procedūrą ir pakartokite tyrimą su nauju testu. Jei problema išlieka, nedelsdami nutraukite tyrimo rinkinio naudojimą ir kreipkitės į vietinį platintoją.

【KOKYBĖS KONTROLĖ】

Teste yra integruota vidinė procedūrinė kontrolė. Kontrolinėje srityje (C) atsirandanti spalvota linija yra vidinė procedūrinė kontrolė. Ji patvirtina pakankamą mėginio tūrį, tinkamą membranos sudrėkinimą ir tinkamą procedūros techniką.

【APRIBOJIMAI】

1. HBsAg greito testo kasetė yra skirta tik profesionaliam in vitro diagnostiniam naudojimui. Testas turi būti naudojamas HBsAg nustatymui žmogaus bendrame kraujyje, serume arba plazmoje. Šiuo kokybiniu tyrimu negalima nustatyti nei kiekybinės vertės, nei HBsAg koncentracijos.
2. HBsAg greito testo kasetė parodo tik HBsAg antikūnų buvimą mėginyje ir neturėtų būti naudojama kaip vienintelis hepatito B virusinės infekcijos diagnozavimo kriterijus.
3. Kitos infekcijos formos, pavyzdžiui, seroneigiama infekcija „lango“ laikotarpiu ir užslėpta hepatito B infekcija, gali būti nepastebėtos atliekant HBsAg tyrimą.
4. Jei tyrimo rezultatai ir klinikiniai simptomai nesutampa, tai turėtų būti patvirtinta ELISA, CMIA arba NAT metodais.
5. HBsAg greitojo testo kasetė negali aptikti mažesnio nei 1 ng/ml HBsAg kiekio mėginiuose. Jei tyrimo rezultatas neigiamas, o klinikiniai simptomai išlieka, rekomenduojama atlikti papildomus tyrimus kitais klinikiniais metodais. Neigiamas rezultatas neatmeta hepatito B viruso infekcijos buvimo galimybės.
6. Hematokritas bendro kraujo mėginyje turi būti nuo 25% iki 65%.

【VEIKSMINGUMO CHARAKTERISTIKOS】

Jautrumas ir specifiškumas

HBsAg greito testo kasete (bendras kraujas / serumas / plazma) buvo ištirti serumo, plazmos ir bendro kraujo mėginiai ir palyginti su CE žymėtu CMIA tyrimu. Gauti rezultatai parodė, kad santykinis HBsAg greito testo (bendras kraujas / serumas / plazma) kasetės jautrumas yra 99,9%, o santykinis specifiškumas yra 99,9%.

Bendro kraujo / serumo / plazmos mėginiai

Mėginio būsena	Mėginio HBsAg būsena	Palyginamasis metodas	Serumo / plazmos mėginiai			Bendro kraujo mėginiai		
			Mėginių skaičius	HBsAg greitasis testas		Mėginių skaičius	HBsAg greitasis testas	
				Teigiamas	Neigiamas		Teigiamas	Neigiamas
HBsAg teigiami mėginiai	Teigiamas	CMIA	722	721	1	50	50	0
Kraujo donorų mėginiai	Neigiamas	CMIA	900	2	898	200	0	200
Klinikiniai (ligoninės) mėginiai	Neigiamas	CMIA	1282	2	1280	30	0	30
Nėščių moterų mėginiai	Neigiamas	CMIA	215	0	215	/	/	/
Interferuojančios substancijos	Neigiamas	CMIA	140	0	140	/	/	/

Santykinis jautrumas =99,87% (95%CI*: 99,28%->99,99%)
Santykinis specifiškumas =99,86% (95%CI*: 99,63%-99,96%)
Bendras tikslumas =99,86% (95% CI*: 99,67%-99,95%) *Pasikliovimo intervalas

Serumo mėginiai

Mėginio būsena	Mėginio HBsAg būsena	Palyginamasis metodas	Serumo mėginiai		
			Mėginių skaičius	HBsAg greitasis testas	
				Teigiamas	Neigiamas
HBsAg teigiami mėginiai	Teigiamas	CMIA	492	492	0
Kraujo donorų mėginiai	Neigiamas	CMIA	800	2	798
Klinikiniai (ligoninės) mėginiai	Neigiamas	CMIA	1062	2	1060
Nėščių moterų mėginiai	Neigiamas	CMIA	215	0	215
Interferuojančios substancijos	Neigiamas	CMIA	140	0	140

Santykinis jautrumas =99,99% (95%CI*: 99,25%->99,99%)
Santykinis specifiškumas =99,82% (95%CI*: 99,54%-99,95%)
Bendras tikslumas =99,85% (95% CI*: 99,62%-99,96%) *Pasikliovimo intervalas

Plazmos mėginiai

Mėginio būsena	Mėginio HBsAg būsena	Palyginamasis metodas	Plazmos mėginiai		
			Mėginių skaičius	HBsAg greitasis testas	
				Teigiamas	Neigiamas
HBsAg teigiami mėginiai	Teigiamas	CMIA	230	229	1
Kraujo donorų mėginiai	Neigiamas	CMIA	100	0	100
Klinikiniai (ligoninės) mėginiai	Neigiamas	CMIA	220	0	220
Nėščių moterų mėginiai	Neigiamas	CMIA	/	/	/
Interferuojančios substancijos	Neigiamas	CMIA	/	/	/

Santykinis jautrumas =99,57% (95%CI*: 97,60%->99,99%)
Santykinis specifiškumas =>99,99% (95%CI*: 98,85%->99,99%)
Bendras tikslumas =99,82% (95% CI*: 98,99%-99,99%) *Pasikliovimo intervalas

Bendro kraujo mėginiai

Mėginio būsena	Mėginio HBsAg būsena	Palyginamasis metodas	Bendro kraujo mėginiai		
			Mėginių skaičius	HBsAg greitasis testas	
				Teigiamas	Neigiamas
HBsAg teigiami mėginiai	Teigiamas	CMIA	50	50	0
Kraujo donorų mėginiai	Neigiamas	CMIA	200	0	200
Klinikiniai (ligoninės) mėginiai	Neigiamas	CMIA	30	0	30
Nėščių moterų mėginiai	Neigiamas	CMIA	/	/	/
Interferuojančios substancijos	Neigiamas	CMIA	/	/	/

Santykinis jautrumas =99,99% (95%CI*: 92,89%->99,99%)
Santykinis specifiškumas =>99,99% (95%CI*: 98,41%->99,99%)

Bendras tikslumas =99,99% (95% CI*: 98,69%-99,99%) *Pasikliovimo intervalas

Serumas ir plazma

Serologiškai teigiamų suporuotų serumo ir plazmos mėginių jautrumas:

HBsAg greitojo testo kasete buvo ištirta 100 serologiškai teigiamų serumo ir plazmos porų. Tyrimų rezultatų koreliacija tarp serumo ir plazmos su HBsAg serologiškai teigiamais mėginiais buvo gera.

Mėginio tipas	**Tirtų mėginių skaičius**	**Teigiamų rezultatų sutapimas atliekant HBsAg greitąjį testą**
Serumas	100	>99,9%(100/100)
Plazma	100	>99,9%(100/100)

Serologiškai teigiamų suporuotų serumo ir plazmos mėginių specifiškumas:

HBsAg greitojo testo kasete buvo ištirta 220 serologiškai neigiamų serumo ir plazmos porų. Tyrimų rezultatų koreliacija tarp serumo ir plazmos su HBsAg serologiškai neigiamais mėginiais buvo gera.

Mėginio tipas	**Tirtų mėginių skaičius**	**Neigiamų rezultatų sutapimas atliekant HBsAg greitąjį testą**
Serumas	220	>99,9%(100/100)
Plazma	220	>99,9%(100/100)

Serokonversiniai paneliai

Naudojant HBsAg greitojo testo kasetę (bendras kraujas / serumas / plazma) buvo ištirta 30 serokonversinių panelių ir palyginta su CE ženklu pažymėto Turklab testo, kaip etaloninio tyrimo, rezultatais. HBsAg greito testo kasetė (bendras kraujas / serumas / plazma) aptikimo pajėgumas panašus į etaloninio tyrimo pajėgumą.

Didelės dozės užkabinimo (kablio) efektas

Kai HBsAg kiekis yra ne didesnis kaip 500 ng/ml, didelės dozės užkabinimo efektas nebuvo stebėtas.

Tyrimo ribose

Preciziškumas tyrimo ribose buvo nustatomas naudojant keturis mėginius: 0 ng/ml, 1 ng/ml, 7 ng/ml ir 20 ng/ml teigiami mėginiai. Tyrimas buvo atliekamas 15 pakartojimų per dieną 5 dienas iš eilės vieno operatoriaus, naudojant 1 partiją HBsAg greitojo testo, 1 partiją buferio. Skirtumų tarp partijų nenustatyta.

Tarp tyrimų

Preciziškumas tarp tyrimų buvo nustatomas naudojant keturis mėginius: 0 ng/ml, 1 ng/ml, 7 ng/ml ir 20 ng/ml teigiami mėginiai. Tyrimas buvo atliekamas 15 pakartojimų per dieną 5 dienas iš eilės 3 skirtingose vietose, naudojant 3 skirtingas HBsAg greitųjų testų partijas (vienoje vietoje - viena partija), trijų operatorių kiekvienoje vietoje. Skirtingų dienų, vietų, partijų ir operatorių skirtumų nenustatyta.

Kryžminis reaktyvumas

HBsAg greito testo kasetė (bendras kraujas / serumas / plazma) buvo tirta su anti-HCV, anti-HEV, anti-Syphilis, anti-EBV, CEA, AFP, PSA, CA15-3, CA19-9, CA125, anti-HAV IgM, anti-HIV, anti-RF, anti-H.pylori, anti-CMV IgG, anti-Rubella IgG, anti-TOXO IgG, anti-HSV 1 IgG, anti-HSV 2 IgG, Dengue NS1 ir Zika NS1 teigiamais mėginiais. Kryžminis reaktyvumas nebuvo stebimas.

Interferuojančios substancijos

Į HBsAg neigiamus ir teigiamus mėginius buvo pridėta šių galimai interferuojančių medžiagų. Nė viena iš tirtų medžiagų nurodytomis koncentracijomis neinterferavo tyrimo.

Acetaminofenas: 20 mg/dl	Kofeinas: 20 mg/dl
Acetilsalicilo rūgštis: 20 mg/dl	Gentiso rūgštis: 20 mg/dl
Askorbo rūgštis: 1 g/dl	Albuminas: 2 g/dl
Kreatinas: 200 mg/dl	Hemoglobinas: 2000mg/dl
Bilirubinas: 0,5 g/dl	Oksalo rūgštis: 60 mg/dl
Kokainas: 20 mg/dl	Metadonas: 20 mg/dl

【LITERATŪROS NUORODOS】

1. Colin W. Shepard, Edgar P. Simard, Lyn Finelli, Anthony E. Fiore, Beth P. Bell, Hepatitis B Virus Infection: Epidemiology and Vaccination, Epidemiologic Reviews, Volume 28, Issue 1, August 2006, Pages 112–125.
2. Ravi Kaul,Chapter 9.17 - Hepatitis, Editor(s): David Wild, The Immunoassay Handbook(Fourth Edition),Elsevier,2013,Pages 901-911.

Simbolių rodyklė

	Susipažinkite su naudojimo instrukcijomis arba elektroninėmis naudojimo instrukcijomis	Σ	Turinio pakanka <n> tyrimų	2°C 30°C	Temperatūros ribos
IVD	In vitro diagnostinė medicinos priemonė	LOT	Partijos kodas	REF	Katalogo numeris
EC REP	Įgaliotas atstovas Europos Bendrijoje		Naudokite iki nurodytos datos		Nenaudokite pakartotinai
	Nenaudokite, jei pakuotė pažeista, skaitykite naudojimo instrukcijas		Gamintojas		Dėmesio

Hangzhou AllTest Biotech Co.,Ltd.
#550,Yinhai Street
Hangzhou Economic & Technological Development Area
Hangzhou, 310018 P.R. China
Web: www.alltests.com.cn Email: info@alltests.com.cn

CE 2934

EC REP
MedNet EC-REP GmbH
Borkstrasse 10,
48163 Muenster,
Germany

Tikslus dokumento vertimas į lietuvių kalbą
Vertėja Akvilė Gegelevičienė
Data 2022-10-10
UAB Diamedica
Gėlių g. 2, Avižieniai, Lietuva

Numeris: 146262000
Įsigaliojimo data: 2022-05-11

HCV Rapid Test Cassette (Whole Blood/Serum/Plasma)

Package Insert

REF IHC-402	English

A rapid test for the qualitative detection of antibodies to Hepatitis C Virus in human whole blood, serum or plasma.
For professional in vitro diagnostic use only.

【INTENDED USE】

The HCV Rapid Test Cassette (Whole Blood/Serum/Plasma) is a rapid chromatographic immunoassay for the qualitative detection of antibody to Hepatitis C Virus in human whole blood, serum or plasma.
The test is intended for professional *in vitro* diagnostic use only. Not for screening.

【SUMMARY】

Hepatitis C is a liver disease caused by the hepatitis C virus (HCV) that causes acute and chronic infection[1,2]. Hepatitis C Virus (HCV) is a small, enveloped, positive-sense, single-stranded RNA Virus. HCV is now known to be the major cause of parenterally transmitted non-A, non-B hepatitis. Antibody to HCV is found in over 80% of patients with well-documented non-A, non-B hepatitis. An estimated 71 million people had chronic hepatitis C infection worldwide in 2015.[3]
Conventional methods fail to isolate the virus in cell culture or visualize it by electron microscope. Cloning the viral genome has made it possible to develop serologic assays that use recombinant antigens. Compared to the first generation HCV EIAs using single recombinant antigen, multiple antigens using recombinant protein and/or synthetic peptides have been added in new serologic tests to avoid nonspecific cross-reactivity and to increase the sensitivity of the HCV antibody tests.
The HCV Rapid Test Cassette (Whole Blood/Serum/Plasma) is a rapid test to qualitatively detect the presence of antibody to HCV in a whole blood, serum or plasma specimen. The test utilizes colloid gold conjugate and recombinant HCV proteins to selectively detect antibody to HCV in whole blood, serum or plasma. The recombinant HCV proteins used in the test kit are encoded by the genes for both structural (nucleocapsid) and non-structural proteins.

【PRINCIPLE】

The HCV Rapid Test Cassette (Whole Blood/Serum/Plasma) is a qualitative, membrane based immunoassay for the detection of antibody to HCV in whole blood, serum or plasma. The membrane is pre-coated with recombinant HCV antigen on the test line region of the test. During testing, the whole blood, serum or plasma specimen reacts with recombinant HCV antigen conjugated colloid gold. The mixture migrates upward on the membrane chromatographically by capillary action to react with recombinant HCV antigen on the membrane and generate a colored line. Presence of this colored line indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a colored line will always appear at the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

【REAGENTS】

The test cassette contains recombinant HCV antigen conjugated colloid gold and HCV antigen coated on the membrane.

【PRECAUTIONS】

- For professional *in vitro* diagnostic use only. Do not use after expiration date.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- Humidity and temperature can adversely affect results.

【STORAGE AND STABILITY】

The kit can be stored at room temperature or refrigerated (2-30 °C). The test cassette is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. **DO NOT FREEZE**. Do not use beyond the expiration date.

【SPECIMEN COLLECTION AND PREPARATION】

- The HCV Rapid Test Cassette (Whole Blood/Serum/Plasma) can be performed using whole blood, serum or plasma.
- **To collect Fingerstick Whole Blood specimens:**
  - Wash the patient's hand with soap and warm water or clean with an alcohol swab. Allow to dry.
  - Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.
  - Puncture the skin with a sterile lancet. Wipe away the first sign of blood.
  - Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.
  - Add the Fingerstick Whole Blood specimen to the test by using a capillary tube:
    - Touch the end of the capillary tube to the blood until filled to approximately 50μL. Avoid air bubbles.
    - Place the bulb onto the top end of the capillary tube, then squeeze the bulb to dispense the whole blood to the specimen well of the test cassette.
- **Venous whole blood:**
  - Collect whole blood specimen into a collection tube (with specified anticoagulant, namely EDTA K2, heparin sodium, sodium citrate or potassium oxalate) according to standard venous blood sampling process. Other anticoagulants may lead to incorrect results. Store whole blood specimen at 2-8 °C for up to 3 days if it is not used immediately after being sampled. Do not freeze whole blood specimen. Before testing, gently shake the blood tube to obtain a homogeneous specimen.
- **Serum:**
  - Collect whole blood specimen into a collection tube without anticoagulant according to standard venous blood sampling process. Leave to settle for 30 minutes for blood coagulation, then centrifuge at 3000rpm for at least 5 minutes to obtain the serum supernatant.
- **Plasma:**
  - Collect whole blood specimen into a collection tube (with specified anticoagulant, namely EDTA K2, heparin sodium, citrate sodium or potassium oxalate) according to standard venous blood sampling process. Gently invert the collection tube for several times and leave to settle for 30 minutes for blood coagulation, then centrifuge at 3000rpm for at least 5 minutes to obtain the plasma supernatant.
- Separate the serum or plasma from blood as soon as possible to avoid hemolysis. Only clear, non-hemolyzed specimens can be used.
- Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8 °C for up to 3 days. For long term storage, specimens should be kept below -20 °C. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 3 days of collection. Do not freeze whole blood specimens. Whole blood collected by fingerstick should be tested immediately.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
- If specimens are to be shipped, they should be packed in compliance with local regulations.

【MATERIALS 】

Materials provided

	Kit size	40T/kits
Components	Tests	40
	Package insert	1
	Droppers	40
	Buffer 3mL (PBS, 0.02% Proclin 300, ≤0.02% NaN_3)	2

Materials required but not provided

• Specimen collection containers • Centrifuge • Timer
• Lancets (for fingerstick whole blood only)
• Heparinized capillary tubes and dispensing bulb (for fingerstick whole blood only)

【DIRECTIONS FOR USE】

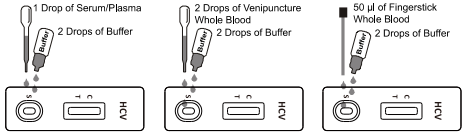
Allow test cassette, specimen, and/or controls to equilibrate to room temperature (15-30 °C) prior to testing.

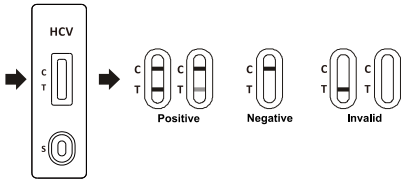
1. Bring the pouch to room temperature before opening it. Remove the test cassette from the sealed pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.
2. Place the cassette on a clean and level surface.

• For **Serum or Plasma** specimen: Hold the dropper vertically and **transfer 1 drop of serum or plasma** (approximately 25 μL) to the **specimen well (S)**, then **add 2 drops of buffer** (approximately 80 μL), and start the timer, see illustration below.
• For **Venous Whole Blood** specimen: Hold the dropper vertically and **transfer 2 drops of whole blood** (approximately 50 μL) to the **specimen well (S)**, then **add 2 drops of buffer** (approximately 80μL), and start the timer. See illustration below.
• For **Fingerstick Whole Blood** specimen: To use a capillary tube: Fill the capillary tube **and transfer approximately 50 μL of fingerstick whole blood specimen** to the **specimen well (S)** of test cassette, then **add 2 drops of buffer** (approximately 80 μL) and start the timer. See illustration below.

3. Wait for the colored line(s) to appear. The test result should be read at **10 minutes**. Do not interpret the result after **20 minutes**.

Note: It is suggested not to use the buffer, beyond 6 months after opening the vial.





【INTERPRETATION OF RESULTS】

(Please refer to the illustration above)

POSITIVE: * Two colored lines appear. One colored line should be in the control region (C) and another colored line should be in the test region (T). Positive result in the Test region indicates detection of HCV antibodies in the specimen.
***NOTE:** The intensity of the color in the test line region (T) will vary depending on the concentration of HCV antibodies present in the specimen. Therefore, any shade of color in the test region should be considered positive.
NEGATIVE: One colored line appears in the control region (C). No colored line appears in the test region (T). Negative result in the Test region indicates negative results of HCV antibody in the specimen.
INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

【QUALITY CONTROL】

Internal procedural controls are included in the test. A colored line appearing in the control region (C) is an internal procedural control. It confirms sufficient specimen volume and correct procedural technique.
Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

【LIMITATIONS】

1. The HCV Rapid Test Cassette (Whole Blood/Serum/Plasma) is not screening device for blood donors.
2. The HCV Rapid Test Cassette (Whole Blood/Serum/Plasma) is for *in vitro* diagnostic use only. This test should be used for the detection of antibodies to HCV in whole blood, serum or plasma specimen.
3. The HCV Rapid Test Cassette (Whole Blood/Serum/Plasma) will only indicate the presence of antibodies to HCV in the specimen and should not be used as the sole criteria for the diagnosis of Hepatitis C viral infection.
4. As with all diagnostic tests, all results must be considered with other clinical information available to the physician.
5. If the test result is negative and clinical symptoms persist, additional follow-up testing using other clinical methods is recommended. A negative result at any time does not preclude the possibility of Hepatitis C Virus infection.
6. The hematocrit of the whole blood should be between 25% and 65%.

【PERFORMANCE CHARACTERISTICS】

Sensitivity and Specificity

The HCV Rapid Test Cassette (Whole Blood/Serum/Plasma) tested serum, plasma and whole blood specimens and was compared with CE marked EIA or CMIA test .The results show that the relative sensitivity of the HCV Rapid Test Cassette (Whole Blood/Serum/Plasma) is 100% and the relative specificity is 100%.

Method			HCV Rapid Test Cassette (Whole Blood/Serum/Plasma)		Agreement
	Result		Positive	Negative	
Predicated Test (EIA or CMIA)	Positive	HCV	397	0	>99.9% (397/397)
		Genotypes 1,2,3,4,5,6	93	0	>99.9% (93/93)
		Total	490	0	>99.9% (490/490)
	Negative	Blood Donation	0	1000	>99.9% (1000/1000)
		Clinical Negative	0	209	>99.9% (209/209)
		Pregnant Woman	0	200	>99.9% (200/200)
		Interference Substance	0	135	>99.9% (135/135)
		Total	0	1544	>99.9% (1544/1544)
Total Result			490	1544	>99.9% (2034/2034)

Sensitivity: 100% (95%CI*=99.4%-100%)
Specificity: 100% (95%CI*=99.8%-100%)
Accuracy: 100% (95%CI*=99.9%-100%) *Confidence Intervals

Sero-conversion Panels

30 sero-conversion panels were studied with HCV Rapid Test Cassette (Whole Blood/ Serum/Plasma) and compared to results from CE marked test as reference assay. HCV Rapid Test Cassette (Whole Blood/Serum/Plasma) has the similar detection capacity as reference assay.

Precision

Intra-Assay

Within-run precision has been determined by using 15 replicates of four specimens: a negative, a HCV low positive, a HCV middle positive and a HCV high positive. The negative, HCV low positive, HCV middle positive and HCV high positive values were correctly identified 100% of the time.

Inter-Assay

Between-run precision has been determined by 15 independent assays on the same four specimens: a negative, a HCV low positive, a middle positive and a HCV high positive. Three different lots of the HCV Rapid Test Cassette (Whole Blood/Serum/Plasma) have been tested using these specimens. The specimens were correctly identified 100% of the time.

Cross-reactivity

The HCV Rapid Test Cassette (Whole Blood/Serum/Plasma) has been tested by HBsAg, HBsAb, HBeAg, HBeAb, HBcAb, anti-Syphilis, anti-EBV, CEA, AFP, PSA, CA15-3, CA19-9, CA125, anti-HAV IgM, anti-HIV, anti-RF, anti-H.pylori, anti-CMV IgG, anti-Rubella IgG, anti-TOXO IgG, anti-HSV 1 IgG，anti-HSV 2 IgG positive and hCG positive specimens. The results showed no cross-reactivity.

Interfering Substances

The following potentially interfering substances were added to HCV negative and positive specimens.

Acetaminophen: 20mg/dL	Caffeine: 20mg/dL
Acetylsalicylic Acid: 20mg/dL	Gentisic Acid: 20mg/dL
Ascorbic Acid: 2g/dL	Albumin: 2g/dL
Creatin: 200mg/dL	Hemoglobin: 1000mg/dL
Bilirubin: 1g/dL	Oxalic Acid: 60mg/dL

None of the substances at the concentration tested interfered in the assay.

【BIBLIOGRAPHY】

1. World Health Organization. New recommendations in the updated WHO guidelines for the screening, care and treatment of persons with chronic hepatitis C infection. Geneva: WHO; 2016. http://www.who.int/hepatitis/publications/hepatitis-c-guidelines-2016/en/.
2. Lavanchy D. The global burden of hepatitis C. Liver Int. 2009;29(s1):74–81.
3. World Health Organization. Global Hepatitis Report, 2017. Geneva; 2017. http://www.who.int/hepatitis/publications/global-hepatitis-report2017/en/. Accessed 6 Oct 2017.

Index of Symbols

	Consult Instructions For Use	Σ	Tests per kit	EC REP	Authorized Representative
IVD	For *in vitro* diagnostic use only		Use by		Do not reuse
2°C 30°C	Store between 2-30°C	LOT	Lot Number	REF	Catalog #
	Do not use if package is damaged		Manufacturer		Caution

Hangzhou AllTest Biotech Co.,Ltd.
#550,Yinhai Street
Hangzhou Economic & Technological Development Area
Hangzhou, 310018 P.R. China
Web: www.alltests.com.cn Email: info@alltests.com.cn

CE 2934

EC REP
MedNet EC-REP GmbH
Borkstrasse 10,
48163 Muenster,
Germany

Number: 146250200
Effective date: 2022-05-16

HCV greito testo kasetė (Bendras kraujas / serumas / plazma) Pakuotės aprašymas

REF IHC-402	Lietuvių k.

Greitasis testas hepatito C viruso antikūnų kokybiniam nustatymui žmogaus kraujyje, serume arba plazmoje.
Tik profesionaliam in vitro diagnostiniam naudojimui.

【PASKIRTIS】

HCV greitojo testo kasetė (bendras kraujas / serumas / plazma) yra greitas chromatografinis imunologinis tyrimas, skirtas kokybiniam antikūnų prieš hepatito C virusą nustatymui žmogaus bendrame kraujyje, serume arba plazmoje.
Testas yra skirtas tik profesionaliam *in vitro* diagnostiniam naudojimui. Neskirta skryningo vykdymui.

【SANTRAUKA】

Hepatitas C yra kepenų liga, kurią sukelia hepatito C virusas (HCV), pasireiškiantis ūmine ar lėtine infekcija[1,2]. Hepatito C virusas (HCV) yra nedidelis, teigiamas, apvalkalą turintis, viengrandės RNR virusas. Yra žinoma, kad HCV yra pagrindinė ne A ir ne B hepatitų, perduodamų per tėvus, priežastis. Daugiau kaip 80% pacientų, sergančių ne A ir ne B hepatitu, randama HCV antikūnų. 2015 m. pasaulyje lėtiniu hepatitu C sirgo 71 milijonas žmonių.[3]
Įprastiniais metodais viruso nepavyksta išskirti ląstelių kultūroje ar vizualizuoti elektroniniu mikroskopu. Klonavus viruso genomą, atsirado galimybė sukurti seroloģinius tyrimus, kuriuose naudojami rekombinantiniai antigenai. Lyginant su pirmos kartos HCV EIA, kuriuose buvo naudojamas vienas rekombinantinis antigenas, siekiant išvengti nespecifinio kryžminio reaktyvumo ir padidinti HCV antikūnų tyrimų jautrumą, naujuose serologiniuose tyrimuose yra naudojami keli rekombinantiniai baltymai ir (arba) sintetiniai peptidai.
HCV greitojo testo kasetė (bendras kraujas / serumas / plazma) yra greitas tyrimas, skirtas kokybiniam HCV antikūnų nustatymui žmogaus bendro kraujo, serumo ar plazmos mėginiuose. Tyrime naudojamas koloidinio aukso konjugatas ir rekombinantiniai HCV baltymai suteikia galimybę selektyviai aptikti antikūnus prieš HCV bendrame kraujyje, serume arba plazmoje. Tyrimo rinkinyje naudojami rekombinantiniai HCV baltymai yra užkoduoti struktūrinių (nukleokapsidės) ir nestruktūrinių baltymų genais.

【PRINCIPAS】

HCV greitojo testo kasetė (bendras kraujas / serumas / plazma) yra kokybinis membraninis imunofermentinis testas, skirtas nustatyti HCV antikūnus bendrame kraujyje, serume arba plazmoje. Membrana yra padengta rekombinantiniu HCV antigenu testo linijos srityje. Tyrimo metu bendras kraujas, serumas arba plazma reaguoja su rekombinantiniu HCV antigenu, konjuguotu su koloidiniu auksu. Membranoje mišinys kapiliariniu būdu chromatografiškai migruoja aukštyn ir reaguoja su rekombinantiniu HCV antigenu membranoje ir sugeneruoja spalvotą liniją. Šios spalvotos linijos buvimas rodo teigiamą rezultatą, o jos nebuvimas - neigiamą rezultatą. Kontrolinės linijos srityje visada atsiranda spalvota linija, rodanti, kad buvo naudotas reikiamas mėginio kiekis ir mėginys tinkamai padengė membraną.

【REAGENTAI】

Testo kasetėje yra rekombinantinis HCV antigenas, konjuguotas su koloidiniu auksu, ir HCV antigenas, padengtas ant membranos.

【ATSARGUMO PRIEMONĖS】

- Tik profesionaliam *in vitro* diagnostiniam naudojimui. Nenaudokite pasibaigus galiojimo datai.
- Nevalgykite, negerkite ir nerūkykite mėginių ar rinkinių tvarkymo vietoje.
- Su visais mėginiais elkitės kaip su potencialiai infekcinėmis medžiagomis. Visos procedūros metu laikykitės nustatytų atsargumo priemonių dėl mikrobiologinio pavojaus ir laikykitės standartinių tinkamo mėginių utilizavimo procedūrų.
- Mėginių tyrimo metu dėvėkite apsauginius drabužius, pvz., laboratorinius chalatus, vienkartines pirštines ir akių apsaugos priemones.
- Drėgmė ir temperatūra gali turėti neigiamos įtakos rezultatams.

【LAIKYMAS IR STABILUMAS】

Rinkinį galima laikyti kambario temperatūroje arba šaldytuve (2-30 °C). Testo kasetė išlieka stabili iki ant pakuotės nurodytos galiojimo pabaigos datos. Iki naudojimo testo kasetė turi būti originalioje sandarioje pakuotėje. **NEUŽŠALDYKITE.** Nenaudokite pasibaigus galiojimo laikui.

【MĖGINIŲ PAĖMIMAS IR PARUOŠIMAS】

- HCV greitojo testo kasetė (bendras kraujas / serumas / plazma) gali būti naudojama su bendro kraujo, serumo ar plazmos mėginiais.
- **Bendro kraujo mėginių iš piršto paėmimas:**
  - Nuplaukite paciento ranką muilu ir šiltu vandeniu arba nuvalykite alkoholyje sudrėkintu tamponu. Leiskite nudžiūti.
  - Pamasažuokite plaštaką neliesdami dūrio vietos, braukdami žemyn ranka link vidurinio arba bevardžio piršto galiuko.
  - Steriliu lancetu atlikite punkciją. Nušluostykite pirmąjį kraują.
  - Švelniai patrinkite ranką nuo riešo per delną iki piršto, kad ant dūrio vietos susidarytų apvalus kraujo lašas.
  - Kapiliariniu mėgintuvėliu paimkite kraujo mėginį:
    - Kapiliariniu mėgintuvėliu lieskite kraują, kol jis prisipildys maždaug 50µl. Venkite oro burbuliukų patekimo.
    - Bendro kraujo mėginį lašintuvu dozuokite į testo kasetės mėginio šulinėlį.
- **Veninis kraujas:**
  - Surinkite bendro kraujo mėginį į mėgintuvėlį (su nurodytu antikoaguliantu, t. y. EDTA K2, heparino natrio druska, natrio citratu arba kalio oksalatu) pagal standartinę veninio kraujo paėmimo procedūrą. Kiti antikoaguliantai gali lemti klaidingus rezultatus. Jei bendro kraujo mėginys nenaudojamas iš karto po mėginio paėmimo, laikykite jį iki 3 dienų 2-8 °C temperatūroje. Neužšaldykite bendro kraujo mėginio. Prieš tyrimą švelniai pakratykite mėgintuvėlį, kad mėginys homogenizuotųsi.
- **Serumas:**
  - Surinkite bendro kraujo mėginį į mėgintuvėlį (su nurodytu antikoaguliantu, t. y. EDTA K2, heparino natrio druska, natrio citratu arba kalio oksalatu) pagal standartinę veninio kraujo paėmimo procedūrą. Palikite nusistovėti 30 minučių, kad kraujas koaguliuotų, tada bent 5 minutes centrifuguokite 3000 sūkių per minutę greičiu, kad gautumėte serumo supernatantą.
- **Plazma:**
  - Surinkite bendro kraujo mėginį į mėgintuvėlį (su nurodytu antikoaguliantu, t. y. EDTA K2, heparino natrio druska, natrio citratu arba kalio oksalatu) pagal standartinę veninio kraujo paėmimo procedūrą. Keletą kartų atsargiai pavartykite mėgintuvėlį ir palikite jį nusistovėti 30 minučių, kad kraujas koaguliuotų, tada bent 5 minutes centrifuguokite 3000 sūkių per minutę greičiu, kad gautumėte plazmos supernatantą.
- Kad išvengtumėte hemolizės, kuo greičiau atskirkite serumą ar plazmą nuo kraujo. Galima naudoti tik skaidrius, ne hemolizuotus mėginius.
- Tyrimas turėtų būti atliekamas iš karto po mėginio paėmimo. Nepalikite mėginių kambario temperatūroje ilgesnį laiką. Serumo ir plazmos mėginiai gali būti laikomi 2-8 °C temperatūroje ne ilgiau kaip 3 dienas. Ilgalaikiam saugojimui mėginiai turi būti laikomi žemesnėje nei -20 °C temperatūroje. Venos punkcijos būdu paimtą bendrą kraują reikia laikyti 2-8 °C temperatūroje, jei tyrimas bus atliekamas per 3 dienas nuo mėginio paėmimo. Neužšaldykite bendro kraujo mėginio. Iš piršto paimti bendro kraujo mėginiai turi būti tiriami nedelsiant.
- Prieš tyrimą mėginiai turi būti kambario temperatūros. Užšaldyti mėginiai prieš tyrimą turi būti pilnai atšildyti ir gerai išmaišyti. Mėginių negalima pakartotinai užšaldyti ir atšildyti.
- Jei mėginiai turi būti transportuojami, jie turi būti supakuoti laikantis vietos taisyklių.

【MEDŽIAGOS 】

Tiekiamos medžiagos

Komponentai	**Rinkinio dydis**	**40 testų rinkinyje**
	Testai	40
	Pakuotės aprašymas	1
	Lašintuvai	40
	Buferis 3ml (PBS, 0,02% Proclin 300, ≤0,02% NaN_3)	2

Reikalingos netiekiamos medžiagos

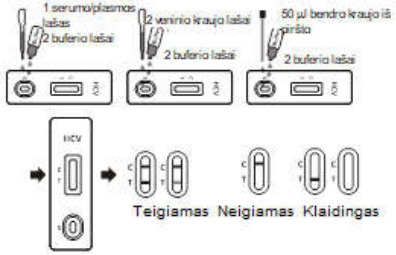
• Mėginių paėmimo konteineriai • Centrifuga • Laikmatis
• Lancetai (tik bendro kraujo paėmimui iš piršto)
• Heparinizuoti kapiliariniai mėgintuvėliai ir lašintuvas (tik bendro kraujo paėmimui iš piršto)

【NAUDOJIMO INSTRUKCIJOS】

Prieš atlikdami tyrimą, leiskite testo kasetei, mėginiui ir (arba) kontrolinėms medžiagoms sušilti iki kambario temperatūros (15-30 °C).

1. Prieš atidarant, pakuotė turi būti kambario temperatūros. Išimkite testo kasetę iš pakuotės ir kuo greičiau ją panaudokite. Geriausi rezultatai gaunami, jei tyrimas atliekamas per vieną valandą.
2. Padėkite kasetę ant švaraus ir lygaus paviršiaus.
• **Serumo ar plazmos** mėginiai: Lašintuvą laikydami vertikaliai **įlašinkite 1 serumo ar plazmos lašą** (apie 25 µl) į **mėginio šulinėlį (S)**, tuomet **įlašinkite 2 buferio lašus** (apie 80 µl) ir įjunkite laikmatį (žr. iliustraciją žemiau).
• **Veninio kraujo** mėginiai: Lašintuvą laikydami vertikaliai **įlašinkite 2 bendro kraujo lašus** (apie 50 µl) į **mėginio šulinėlį (S)**, tuomet **įlašinkite 2 buferio lašus** (apie 80 µl) ir įjunkite laikmatį. Žr. iliustraciją žemiau.
•**Bendro kraujo mėginiai iš piršto:** Kapiliarinio mėgintuvėlio naudojimas: Užpildykite kapiliarinį mėgintuvėlį ir **įlašinkite apie 50 µl bendro kraujo iš piršto mėginio** į **mėginio šulinėlį (S)**, tuomet **įlašinkite 2 buferio lašus** (apie 80 µl) ir įjunkite laikmatį. Žr. iliustraciją žemiau.
3. Palaukite, kol atsiras spalvota linija (-os). Tyrimo rezultatas turėtų būti nuskaitytas po **10 minučių**. Po **20 minučių** rezultato neinterpretuokite.

Pastaba. Rekomenduojama buferio nenaudoti ilgiau kaip 6 mėnesius po buteliuko atidarymo.



【REZULTATŲ INTERPRETAVIMAS】

(Žr. iliustraciją pirmiau)

TEIGIAMAS: *atsiranda dvi spalvotos linijos. Viena spalvota linija turėtų būti kontrolinėje srityje (C), o kita spalvota linija - tyrimo srityje (T). Teigiamas tyrimo srities rezultatas rodo, kad mėginyje aptikti HCV antikūnai.
***PASTABA.** Spalvos intensyvumas tyrimo linijos srityje (T) priklauso nuo HCV antikūnų koncentracijos mėginyje. Todėl bet koks spalvos atspalvis tyrimo srityje turėtų būti laikomas teigiamu.
NEIGIAMAS: Kontrolinėje srityje (C) atsiranda viena spalvota linija. Tyrimo srityje (T) spalvota linija neatsiranda. Neigiamas rezultatas tyrimo srityje rodo, jog HCV antikūnų mėginyje nėra.
NEGALIOJANTIS: Kontrolinė linija neatsiranda. Nepakankamas mėginio tūris arba netinkami procedūriniai metodai yra labiausiai tikėtinos kontrolinės linijos neatsiradimo priežastys. Peržiūrėkite procedūrą ir pakartokite tyrimą su nauju testu. Jei problema išlieka, nedelsdami nutraukite tyrimo rinkinio naudojimą ir kreipkitės į vietinį platintoją.

【KOKYBĖS KONTROLĖ】

Teste yra integruota vidinė procedūrinė kontrolė. Kontrolinėje srityje (C) atsirandanti spalvota linija yra vidinė procedūrinė kontrolė. Ji patvirtina pakankamą mėginio tūrį ir tinkamą procedūros techniką.
Kontrolinės standartinės medžiagos su šiuo rinkiniu nepateikiamos, tačiau rekomenduojama atlikti teigiamų ir neigiamų kontrolinių mėginių tyrimus, nes tai yra gera laboratorinė praktika, kad būtų patvirtinta tyrimo procedūra ir patikrintas tinkamas tyrimo atlikimas.

【APRIBOJIMAI】

1. HCV greitojo testo kasetė (bendras kraujas / serumas / plazma) nėra skirta kraujo donorų skryningo atlikimui.
2. HCV greitojo testo kasetė (bendras kraujas / serumas / plazma) yra skirta tik *in vitro* diagnostiniam naudojimui. Šis testas turėtų būti naudojamas HCV antikūnams nustatyti bendro kraujo, serumo ar plazmos mėginiuose.
3. HCV greitojo testo kasetė (bendras kraujas / serumas / plazma) parodo tik HCV antikūnų buvimą mėginyje ir neturėtų būti naudojama kaip vienintelis hepatito C virusinės infekcijos diagnozavimo kriterijus.
4. Kaip ir atliekant visus diagnostinius tyrimus, visi rezultatai turi būti vertinami kartu su kita gydytojo turima klinikine informacija.
5. Jei tyrimo rezultatas neigiamas, o klinikiniai simptomai išlieka, rekomenduojama atlikti papildomus tyrimus kitais klinikiniais metodais. Neigiamas rezultatas bet kuriuo metu neatmeta hepatito C viruso infekcijos buvimo galimybės.
6. Hematokritas bendro kraujo mėginyje turi būti nuo 25% iki 65%.

【VEIKSMINGUMO CHARAKTERISTIKOS】

Jautrumas ir specifiškumas

HCV greito testo kasete (bendras kraujas / serumas / plazma) buvo ištirti srumo, plazmos ir bendro kraujo mėginiai ir palyginti su CE žymėtais EIA ar CMIA tyrimais. Gauti rezultatai parodė, kad santykinis HCV greito testo (bendras kraujas / serumas / plazma) kasetės jautrumas yra 100% ir santykinis specifiškumas yra 100%.

Metodas			**HCV greito testo kasetė (bendras kraujas / serumas / plazma)**		**Atitikimas**
	Rezultatas		**Teigiamas**	**Neigiamas**	
Numatytas tyrimas (EIA ar CMIA)	Teigiamas	HCV	397	0	>99,9% (397/397)
		Genotipai 1,2,3,4,5,6	93	0	>99,9% (93/93)
		Iš viso	490	0	>99,9% (490/490)
	Neigiamas	Kraujo donorystė	0	1000	>99,9% (1000/1000)
		Kliniškai neigiamas	0	209	>99,9% (209/209)
		Nėščios moterys	0	200	>99,9% (200/200)
		Interferuojančios substancijos	0	135	>99,9% (135/135)
		Iš viso	0	1544	>99,9% (1544/1544)
Bendras rezultatas			490	1544	>99,9% (2034/2034)

Jautrumas: 100% (95%CI*=99,4%-100%)
Specifiškumas: 100% (95%CI*=99,8%-100%)
Tikslumas: 100% (95%CI*=99,9%-100%) *Pasikliovimo intervalas

Serokonversiniai paneliai

Naudojant HCV greitojo testo kasetę (bendras kraujas / serumas / plazma) buvo ištirta 30 serokonversinių panelių ir palyginta su CE ženklu pažymėto testo, kaip etaloninio tyrimo, rezultatais. HCV greito testo kasetė (bendras krauajs / serumas / plazma) aptikimo pajėgumas panašus į etaloninio tyrimo pajėgumą.

Preciziškumas

Tyrimo ribose

Preciziškumas tyrimo ribose buvo nustatomas naudojant 15 keturių mėginių kartotinių: neigiamą, HCV silpnai teigiamą, HCV vidutiniškai teigiamą ir HCV stipriai teigiamą. 100% atvejų, neigiamos, HCV silpnai teigiamos, HCV vidutiniškai teigiamos ir HCV stipriai teigiamos vertės buvo identifikuotos teisingai.

Tarp tyrimų

Preciziškumas tarp tyrimų buvo nustatomas atliekant 15 nepriklausomų tyrimų su tais pačiais keturiais mėginiais: neigiamu, HCV silpnai teigiamu, HCV vidutiniškai teigiamu ir HCV stipriai teigiamu. Šie mėginiai buvo tirti naudojant tris skirtingas HCV greito testo kasetės (bendras kraujas / serumas / plazma) partijas. 100% atvejų mėginiai buvo identifikuoti teisingai.

Kryžminis reaktyvumas

HCV greito testo kasetė (bendras kraujas / serumas / plazma) buvo tirta su HBsAg, HBsAb, HBeAg, HBeAb, HBcAb, anti-*Syphilis*, anti-EBV, CEA, AFP, PSA, CA15-3, CA19-9, CA125, anti-HAV IgM, anti-ŽIV, anti-RF, anti-*H.pylori*, anti-CMV IgG, anti-*Rubella* IgG, anti-TOXO IgG, anti-HSV 1 IgG, anti-HSV 2 IgG teigiamais ir hCG teigiamais mėginiais. Kryžminio reaktyvumo rezultatai nebuvo gauti.

Interferuojančios substancijos

Į HCV neigiamus ir teigiamus mėginius buvo pridėta šių galimai interferuojančių medžiagų.

Acetaminofenas: 20mg/dl	Kofeinas: 20mg/dl
Acetilsalicilo rūgštis: 20mg/dl	Gentiso rūgštis: 20mg/dl
Askorbo rūgštis: 2g/dl	Albuminas: 2g/dl
Kreatinas: 200mg/dl	Hemoglobinas: 1000mg/dl
Bilirubinas: 1g/dl	Oksalo rūgštis: 60mg/dl

Nė viena iš tirtų medžiagų nurodytomis koncentracijomis neinterferavo tyrimo.

【LITERATŪROS NUORODOS】

1. World Health Organization. New recommendations in the updated WHO guidelines for the screening, care and treatment of persons with chronic hepatitis C infection. Geneva: WHO; 2016. http://www.who.int/hepatitis/publications/hepatitis-c-guidelines-2016/en/.
2. Lavanchy D. The global burden of hepatitis C. Liver Int. 2009;29(s1):74–81.
3. World Health Organization. Global Hepatitis Report, 2017. Geneva; 2017. http://www.who.int/hepatitis/publications/global-hepatitis-report2017/en/. Accessed 6 Oct 2017.

Simbolių rodyklė

Skaitykite naudojimo instrukcijas		Tyrimai rinkinyje		Įgaliotas atstovas	
Tik *in vitro* diagnostiniam naudojimui	IVD	Naudokite iki nurodytos datos		Nenaudokite pakartotinai	
Laikykite 2-30°C temperatūroje	2°C 30°C	Partijos numeris	LOT	Katalogo numeris	REF
Nenaudokite, jei pakuotė pažeista		Gamintojas		Dėmesio	

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Hangzhou Economic & Technological Development Area
Hangzhou, 310018 P.R. China
Web: www.alltests.com.cn Email: info@alltests.com.cn

CE 2934

EC REP
MedNet EC-REP GmbH
Borkstrasse 10,
48163 Muenster,
Germany

Numeris: 146250200
Įsigaliojimo data: 2022-05-16

Tikslus dokumento vertimas į lietuvių kalbą
Vertėja Akvilė Gegelevičienė
Data 2022-08-31
UAB Diamedica
Gėlių g. 2, Avižieniai, Lietuva

HIV 1.2 Rapid Test Cassette (Whole Blood/Serum/Plasma) Package Insert

REF IHI-402	English

A rapid test for the diagnosis of Human Immunodeficiency Virus to detect antibodies to HIV type 1 and type 2 qualitatively in human whole blood, serum or plasma.
For professional in vitro diagnostic use only.

【INTENDED USE】

The HIV1.2 Rapid Test Cassette (Whole Blood/Serum/Plasma) is a rapid chromatographic immunoassay for the qualitative detection of antibodies to Human Immunodeficiency Virus (HIV) type 1 and type 2 in human whole blood, serum or plasma to aid in the diagnosis of HIV infection.

【SUMMARY】

Human immunodeficiency virus (HIV) infection is one of the main causes of morbidity and mortality worldwide, with most of the disease concentrated in sub-Saharan Africa. As the infection often takes hold in adults who are in the prime of their economic productivity, HIV infection has dramatically altered the economies of many countries[1].

HIV includes a diverse collection of viruses, including HIV type 1 (HIV-1) and HIV-2. HIV-1 is more prevalent and more pathogenic than HIV-2 and is responsible for the vast majority of the global pandemic[1].The HIV virus is a retrovirus that is able to integrate a DNA copy of the viral genome into the DNA of the host cells[2].

The HIV 1.2 Rapid Test Cassette (Whole Blood/Serum/Plasma) is a rapid test to qualitatively detect the presence of antibody to HIV 1 and/or HIV 2 in whole blood, serum or plasma specimen. The test utilizes latex conjugate and multiple recombinant HIV proteins to selectively detect antibodies to the HIV 1.2 in whole blood, serum or plasma.

【PRINCIPLE】

The HIV 1.2 Rapid Test Cassette (Whole Blood/Serum/Plasma) is a qualitative, membrane based immunoassay for the detection of antibodies to HIV 1.2 in whole blood, serum or plasma. The membrane is pre-coated with recombinant HIV antigens. During testing, the whole blood, serum or plasma specimen reacts with HIV antigen coated particles in the test. The mixture then migrates upward on the membrane chromatographically by capillary action and reacts with recombinant HIV antigen on the membrane in the test line region. If the specimen contains antibodies to HIV 1 and/or HIV 2, a colored line will appear in the test line region, indicating a positive result. If the specimen does not contain HIV 1 and/or HIV 2 antibodies, a colored line will not appear in the test line region, indicating a negative result. To serve as a procedural control, a colored line will always appear in the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

【REAGENTS】

The test contains HIV1.2 recombinant antigens coated particles and HIV1.2 recombinant antigens coated on the membrane.

【PRECAUTIONS】

- For professional *in vitro* diagnostic use only. Do not use after expiration date.
- Do not eat, drink or smoke in the area where the specimens or tests are handled.
- Do not use test if pouch is damaged.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout all procedures and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- The used test should be discarded according to local regulations.
- Humidity and temperature can adversely affect results.

【STORAGE AND STABILITY】

Store as packaged in the sealed pouch either at room temperature or refrigerated (2-30°C). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use after the expiration date.

【SPECIMEN COLLECTION AND PREPARATION】

- The HIV 1.2 Rapid Test Cassette (Whole Blood/Serum/Plasma) can be performed using Whole Blood (from venipuncture or fingerstick), serum or plasma.
- To collect Fingerstick Whole Blood specimens:
  - Wash the patient's hand with soap and warm water or clean with an alcohol swab. Allow to dry.
  - Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.
  - Puncture the skin with a sterile lancet. Wipe away the first sign of blood.
  - Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.
  - Add the Fingerstick Whole Blood specimen to the test by using a capillary tube:
    - Touch the end of the capillary tube to the blood until filled to approximately 50μL. Avoid air bubbles.
    - Place the bulb onto the top end of the capillary tube, then squeeze the bulb to dispense the whole blood to the specimen well of the test cassette.
  - Add the Fingerstick Whole Blood specimen to the test by using hanging drops:
    - Position the patient's finger so that the drop of blood is just above the specimen well of the test Cassette.
    - Allow 2 hanging drops of fingerstick whole blood to fall into the center of the specimen well on the test Cassette, or move the patient's finger so that the hanging drop touches the center of the specimen well. Avoid touching the finger directly to the specimen well.
- Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear non-hemolyzed specimens.
- Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 3 days, for long term storage, specimens should be kept below -20°C. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. Do not freeze whole blood specimens. Whole blood collected by fingerstick should be tested immediately.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
- If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.
- EDTA K2, Heparin sodium, Citrate sodium and Potassium Oxalate can be used as the anticoagulant for collecting the specimen.
- Plasma can be obtained by centrifugation for 3 minutes 3000rpm or by static anticoagulant tube to supermatant.

【MATERIALS】

Materials provided

•Test Cassettes •Droppers •Buffer •Package insert

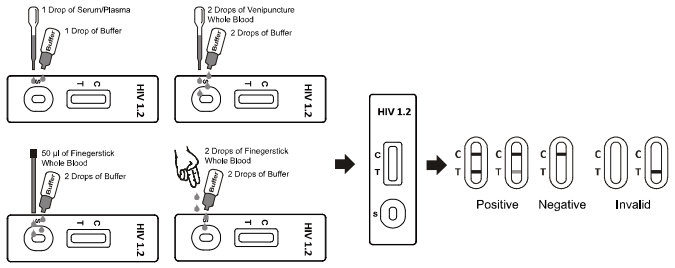
Materials required but not provided

•Specimen collection containers •Timer •Centrifuge

【DIRECTIONS FOR USE】

Allow the test, specimen, buffer and/or controls to reach room temperature (15-30°C) prior to testing.

1. Remove the test cassette from the sealed pouch and use it as soon as possible.
2. Place the Cassette on a clean and level surface.
   For **Serum or Plasma** specimen: Hold the dropper vertically and **transfer 1 drop of serum or plasma** (approximately 25μL) to the specimen well (S), then **add 1 drop of buffer** (approximately 40 μL),and start the timer, see illustration below.
   For **Venipuncture Whole Blood** specimen: Hold the dropper vertically and **transfer 2 drops of whole blood** (approximately 50μL) to the specimen well (S), then **add 2 drops of buffer** (approximately 80μL), and start the timer. See illustration below.
   For **Fingerstick Whole Blood** specimen:
   - To use a capillary tube: Fill the capillary tube **and transfer approximately 50μL of fingerstick whole blood specimen** to the specimen well (S) of test Cassette, then **add 2 drops of buffer** (approximately 80 μL) and start the timer. See illustration below.
   - To use hanging drops: Allow **2 hanging drops of fingerstick whole blood specimen** (approximately 50μL) to fall into the specimen well (S) of test Cassette, then **add 2 drops of buffer** (approximately 80 μL) and start the timer. See illustration below.
3. Wait for the colored line(s) to appear. **Read results at 10 minutes.** Do not interpret the result after **20 minutes**.



【INTERPRETATION OF RESULTS】

(Please refer to the illustration above)

POSITIVE:*Two lines appear. One colored line should be in the control line region (C) and another colored line should be in the test line region (T).

***NOTE:** The intensity of the color in the test line region (T) will vary depending on the concentration of HIV antibodies present in the specimen. Therefore, any shade of color in the test line region (T) should be considered positive.

NEGATIVE: One colored line appears in the control line region (C). No line appears in the test line region (T).

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test Cassette immediately and contact your local distributor.

【QUALITY CONTROL】

A procedural control is included in the test. A colored line appearing in the control line region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

Control standards are not supplied with this test Cassette; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

【LIMITATIONS】

1. The HIV 1.2 Rapid Test Cassette (Whole Blood/Serum/Plasma) is for *in vitro* diagnostic use only. The test should be used for the detection of *HIV* antibodies in whole blood, serum or plasma specimens only. Neither the quantitative value nor the rate of increase in *HIV* antibodies can be determined by this qualitative test.
2. The HIV 1.2 Rapid Test Cassette (Whole Blood/Serum/Plasma) will only indicate the presence of HIV antibodies in the specimen and should not be used as the sole criteria for the diagnosis of HIV infection.
3. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
4. If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at any time preclude the possibility of *HIV* infection.

【EXPECTED VALUES】

The HIV 1.2 Rapid Test Cassette (Whole Blood/Serum/Plasma) has been compared with a leading commercial EIA or CMIA HIV kit. The correlation between these two systems is 99.9%.

【PERFORMANCE CHARACTERISTICS】

Sensitivity and Specificity

The HIV 1.2 Rapid Test Cassette (Whole Blood/Serum/Plasma) has correctly identified specimens of a seroconversion panel and has been compared to a leading commercial EIA HIV test, other rapid test or CMIA using clinical specimens. The results show that the relative sensitivity of the HIV 1.2 Rapid Test Cassette (Whole Blood/Serum/Plasma) is >99.9% and the relative specificity is 99.9%.

Method			IHI-402 Rapid Test Cassette (Whole Blood/Serum/Plasma)		Agreement
	Result		Positive	Negative	
Predicated Test (EIA or CIMA)	Positive	HIV-1	403	1	99.8% (403/404)
		HIV-2	100	0	>99.9% (100/100)
		Subtype	42	0	>99.9% (42/42)
		Total	545	1	99.8% (545/546)
	Negative	Blood Donations	0	1000	>99.9% (1000/1000)
		Pregnant Women	0	200	>99.9% (200/200)
		Clinical Negative	0	201	>99.9% (201/201)
		Total	0	1401	>99.9% (1401/1401)
Total Result			545	1402	99.9% (1946/1947)

Relative sensitivity: 99.8% (95%CI*: 99.0%~>99.9%);
Relative specificity:100% (95%CI*: 99.8%~100%);
Accuracy: 99.9% (95%CI*: 99.7%~>99.9%). *Confidence Intervals

Precision

Intra-Assay

Within-run precision has been determined by using 15 replicates of four specimens: a negative, a low positive, a middle positive and a high positive. One Lot of the HIV 1.2 Rapid Test Cassette (Whole Blood/Serum/Plasma) have been tested over a 10-day period using negative, low positive, middle positive and high positive specimens. The specimens were correctly identified >99% of the time.

Inter-Assay

Between-run precision has been determined by 15 independent assays on the same four specimens: a negative, a low positive, a middle positive and a high positive. Three different lots of the HIV 1.2 Rapid Test Cassette (Whole Blood/Serum/Plasma) have

been tested over a 3-day period using negative, low positive, middle positive and high positive specimens. The specimens were correctly identified >99% of the time.

Cross-reactivity

The HIV 1.2 Rapid Test Cassette(Whole Blood/Serum/Plasma) has been tested by HBsAg, HBsAb, HBeAg, HBeAb, HBcAb, anti-Syphilis, anti-EBV, CEA, AFP, PSA, CA15-3, CA19-9, CA125, anti-HAV IgM, anti-HCV, anti-RF, anti-H.pylori, anti-CMV IgG, anti-Rubella IgG, anti-TOXO IgG, anti-HSV 1 IgG and anti-HSV 2 IgG positive specimens. The results showed no cross-reactivity.

Interfering Substances

The following potentially interfering substances were added to HIV negative and positive specimens.

Acetaminophen: 20 mg/dL	Caffeine: 20 mg/dL
Acetylsalicylic Acid: 20 mg/dL	Gentisic Acid: 20 mg/dL
Ascorbic Acid: 2g/dL	Albumin: 2 g/dL
Creatin: 200 mg/dL	Hemoglobin:1100mg/dL
Bilirubin: 1g/dL	Oxalic Acid: 600mg/dL

None of the substances at the concentration tested interfered in the assay.

【BIBLIOGRAPHY】

1. Deeks, S., Overbaugh, J., Phillips, A. et al. HIV infection. Nat Rev Dis Primers 1, 15035 (2015). https://doi.org/10.1038/nrdp.2015.35
2. Salehi B, Kumar N V A, Şener B, et al. Medicinal plants used in the treatment of human immunodeficiency virus[J]. International journal of molecular sciences, 2018, 19(5): 1459.

Index of Symbols

	Consult instructions for use or consult electronic instructions for use		Contains sufficient for <n> tests	2°C 30°C	Temperature limit
IVD	*In vitro* diagnostic medical device	LOT	Batch code	REF	Catalogue number
EC REP	Authorized representative in the European Community		Use-by date		Do not re-use
	Do not use if package is damaged and consult instructions for use		Manufacturer		Caution

Hangzhou AllTest Biotech Co.,Ltd.
#550,Yinhai Street
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CE 2934

EC REP
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Number: 146250100
Effective date:2022-05-13

HIV 1.2 greito testo kasetė (Bendras kraujas / serumas / plazma) Pakuotės aprašymas

REF IHI-402	Lietuvių k.

Greitasis žmogaus imunodeficito viruso diagnostikos testas, skirtas kokybiškai nustatyti 1 ir 2 tipo ŽIV antikūnus žmogaus bendrame kraujyje, serume arba plazmoje.
Tik profesionaliam in vitro diagnostiniam naudojimui.

【PASKIRTIS】

HIV1.2 greitojo testo kasetė (bendras kraujas/serumas/plazma) yra greitas chromatografinis imunofermentinis tyrimas, skirtas kokybiškai nustatyti žmogaus imunodeficito viruso (ŽIV) 1 ir 2 tipo antikūnus žmogaus bendrame kraujyje, serume arba plazmoje, siekiant padėti diagnozuoti ŽIV infekciją.

【SANTRAUKA】

Žmogaus imunodeficito viruso (ŽIV) infekcija yra viena iš pagrindinių sergamumo ir mirtingumo priežasčių visame pasaulyje, o daugiausia šios ligos atvejų yra Afrikoje į pietus nuo Sacharos. Kadangi šia infekcija dažnai užsikrečia suaugusieji, kurie yra ekonominio produktyvumo viršūnėje, ŽIV infekcija smarkiai pakeitė daugelio šalių ekonomiką[1].

Egzistuoja 1 tipo ŽIV (ŽIV-1) ir ŽIV-2. ŽIV-1 yra labiau paplitęs ir patogeniškesnis nei ŽIV-2 ir yra atsakingas už didžiąją dalį pasaulinės pandemijos[1]. ŽIV virusas yra retrovirusas, galintis integruoti viruso genomo DNR kopiją į ląstelės šeimininkės DNR[2].

HIV 1.2 greito testo kasetė (bendras kraujas / serumas / plazma) yra greitas tyrimas, skirtas kokybiniam antikūnų prieš ŽIV 1 ir (ar) ŽIV 2 nustatymui žmogaus bendro kraujo, serumo ar plazmos mėginiuose. Tyrime naudojamas latekso konjugatas ir keli rekombinantiniai ŽIV baltymai, kad būtų galima selektyviai aptikti antikūnus prieš ŽIV 1.2 bendrame kraujyje, serume arba plazmoje.

【PRINCIPAS】

HIV 1.2 in greitojo testo kasetė (bendras kraujas / serumas / plazma) yra kokybinis membraninis imunofermentinis testas, skirtas nustatyti antikūnus prieš ŽIV 1.2 bendrame kraujyje, serume arba plazmoje. Membrana yra padengta rekombinantiniais ŽIV antigenais. Tyrimo metu bendras kraujas, serumas arba plazma reaguoja su ŽIV antigenu padengtomis dalelėmis. Membranoje mišinys kapiliariniu būdu chromatografiškai migruoja aukštyn ir reaguoja su rekombinantiniu ŽIV antigenu membranoje ir sugeneruoja spalvotą liniją. Jei mėginyje yra ŽIV 1 ir (arba) ŽIV 2 antikūnų, testo linijos srityje atsiras spalvota linija, rodanti teigiamą rezultatą. Jei mėginyje nėra ŽIV 1 ir (arba) ŽIV 2 antikūnų, testo linijos srityje spalvota linija neatsiras, rezultatas bus neigiamas. Kontrolinės linijos srityje visada atsiranda spalvota linija, rodanti, kad buvo naudotas reikiamas mėginio kiekis ir mėginys tinkamai padengė membraną.

【REAGENTAI】

Testą sudaro ŽIV1.2 rekombinantiniais antigenais padengtos dalelės ir ŽIV1.2 rekombinantiniais antigenais padengta membrana.

【ATSARGUMO PRIEMONĖS】

- Tik profesionaliam in vitro diagnostiniam naudojimui. Nenaudokite pasibaigus galiojimo datai.
- Nevalgykite, negerkite ir nerūkykite mėginių ar rinkinių tvarkymo vietoje.
- Nenaudokite, jei pakuotė pažeista.
- Su visais mėginiais elkitės kaip su potencialiai infekcinėmis medžiagomis. Visos procedūros metu laikykitės nustatytų atsargumo priemonių dėl mikrobiologinio pavojaus ir laikykitės standartinių tinkamo mėginių utilizavimo procedūrų.
- Mėginių tyrimo metu dėvėkite apsauginius drabužius, pvz., laboratorinius chalatus, vienkartines pirštines ir akių apsaugos priemones.
- Panaudoti testai turi būti išmetami laikantis vietinių taisyklių.
- Drėgmė ir temperatūra gali turėti neigiamos įtakos rezultatams.

【LAIKYMAS IR STABILUMAS】

Laikykite supakuotą sandariai uždarytame maišelyje kambario temperatūroje arba šaldytuve (2-30 °C). Testo kasetė išlieka stabili iki ant pakuotės nurodytos galiojimo pabaigos datos. Iki naudojimo testo kasetė turi būti originalioje sandarioje pakuotėje. **NEUŽŠALDYKITE.** Nenaudokite pasibaigus galiojimo datai.

【MĖGINIŲ PAĖMIMAS IR PARUOŠIMAS】

- HIV 1.2 greitojo testo kasetė (bendras kraujas / serumas / plazma) gali būti naudojama su bendro kraujo (paimto iš venos ar piršto), serumo ar plazmos mėginiais.
- Bendro kraujo mėginių iš piršto paėmimas:
  - Nuplaukite paciento ranką muilu ir šiltu vandeniu arba nuvalykite alkoholyje sudrėkintu tamponu. Leiskite nudžiūti.
  - Pamasažuokite plaštaką neliesdami dūrio vietos, braukdami žemyn ranka link vidurinio arba bevardžio piršto galiuko.
  - Steriliu lancetu atlikite punkciją. Nušluostykite pirmąjį kraują.
  - Švelniai patrinkite ranką nuo riešo per delną iki piršto, kad ant dūrio vietos susidarytų apvalus kraujo lašas.
  - Kapiliariniu mėgintuvėliu paimkite kraujo mėginį:
    - Kapiliariniu mėgintuvėliu lieskite kraują, kol jis prisipildys maždaug 50µl. Venkite oro burbuliukų patekimo.
    - Bendro kraujo mėginį lašintuvu dozuokite į testo kasetės mėginio šulinėlį.
  - Kraujo lašus nuo piršto lašinkite į testo mėginio šulinėlį:
    - Laikykite paciento pirštą taip, kad kraujo lašas atsidurtų tiesiai virš testo kasetės šulinėlio.
    - Leiskite 2 kabantiems lašams bendro kraujo iš piršto įlašėti į mėginio šulinėlio centrą ant kasetės arba pajudinkite paciento pirštą taip, kad kabantis lašas paliestų mėginio šulinėlio centrą. Neleiskite, kad pirštas tiesiogiai prisiliestų prie mėginio šulinėlio.
- Kad išvengtumėte hemolizės, kuo greičiau atskirkite serumą ar plazmą nuo kraujo. Galima naudoti tik skaidrius, nehemolizuotus mėginius.
- Tyrimas turėtų būti atliekamas iš karto po mėginio paėmimo. Nepalikite mėginių kambario temperatūroje ilgesnį laiką. Serumo ir plazmos mėginiai gali būti laikomi 2-8°C temperatūroje ne ilgiau kaip 3 dienas, jei mėginiai laikomi ilgai, juos reikia laikyti žemesnėje nei -20 °C temperatūroje. Venos punkcijos būdu paimtą bendrą kraują reikia laikyti 2-8 °C temperatūroje, jei tyrimas turi būti atliktas per 2 dienas nuo paėmimo. Neužšaldykite bendro kraujo mėginio. Iš piršto paimti bendro kraujo mėginiai turi būti tiriami nedelsiant.
- Prieš tyrimą mėginiai turi būti kambario temperatūros. Užšaldyti mėginiai prieš tyrimą turi būti pilnai atšildyti ir gerai išmaišyti. Mėginių negalima pakartotinai užšaldyti ir atšildyti.
- Jei mėginiai turi būti transportuojami, jie turi būti supakuoti laikantis vietos taisyklių dėl etiologinių agentų transportavimo.
- EDTA K2, natrio heparinas, natrio citratas ir kalio oksalatas gali būti naudojami kaip antikoaguliantai mėginiui paimti.
- Plazmą galima centrifuguoti 3 minutes 3000 aps./min. arba naudoti statinį mėgintuvėlį su antikoaguliantu, kad būtų galima gauti supernatantą.

【MEDŽIAGOS 】

Tiekiamos medžiagos

•Testo kasetės •Lašintuvai •Buferis •Pakuotės aprašymas

Reikalingos netiekiamos medžiagos

•Mėginio surinkimo konteineris •Laikmatis •Centrifuga

【NAUDOJIMO INSTRUKCIJOS】

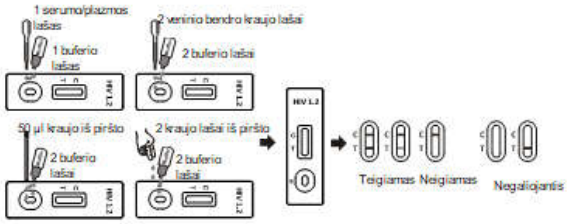
Prieš tyrimą testas, mėginys ir buferis turi pasiekti kambario temperatūrą (15-30°C).

1. Išimkite testo kasetę iš pakuotės ir kuo greičiau ją panaudokite.
2. Padėkite kasetę ant švaraus ir lygaus paviršiaus.

   Serumo ar plazmos mėginiai: Lašintuvą laikydami vertikaliai **įlašinkite 1 serumo ar plazmos lašą** (apie 25 µl) į mėginio šulinėlį (S), tuomet **įlašinkite 1 buferio lašą** (apie 40 µl) ir įjunkite laikmatį (žr. iliustraciją žemiau).

   Veninio bendro kraujo mėginiai: Lašintuvą laikydami vertikaliai **įlašinkite 2 bendro kraujo lašus** (apie 50 µl) į **mėginio šulinėlį (S)**, tuomet **įlašinkite 2 buferio lašus** (apie 80 µl) ir įjunkite laikmatį. Žr. iliustraciją žemiau.

   Bendro kraujo mėginiai iš piršto:
   - Kapiliarinio mėgintuvėlio naudojimas: Užpildykite kapiliarinį mėgintuvėlį ir **įlašinkite apie 50 µl bendro kraujo iš piršto mėginio** į kasetės mėginio šulinėlį (S), tuomet **įlašinkite 2 buferio lašus** (apie 80 µl) ir įjunkite laikmatį. Žr. iliustraciją žemiau.
   - Naudojant kabančius kraujo lašus: Įlašinkite **2 nuo piršto kabančius bendro kraujo lašus** į kasetės mėginio šulinėlį (S), tuomet **įlašinkite 2 buferio lašus** (apie 80 µl) ir įjunkite laikmatį. Žr. iliustraciją žemiau.
3. Palaukite, kol atsiras spalvota linija (-os). **Rezultatus nuskaitykite po 10 minučių.** Po **20 minučių** rezultato neinterpretuokite.



【REZULTATŲ INTERPRETAVIMAS】

(Žr. iliustraciją aukščiau)

TEIGIAMAS: *atsiranda dvi spalvotos linijos. Viena spalvota linija turėtų būti kontrolinėje srityje (C), o kita spalvota linija - tyrimo srityje (T).

***PASTABA.** Spalvos intensyvumas tyrimo linijos srityje (T) priklauso nuo ŽIV antikūnų koncentracijos mėginyje. Todėl bet koks spalvos atspalvis tyrimo srityje (T) turėtų būti laikomas teigiamu.

NEIGIAMAS: Kontrolinėje srityje (C) atsiranda viena spalvota linija. Tyrimo srityje (T) spalvota linija neatsiranda.

NEGALIOJANTIS: Kontrolinė linija neatsiranda. Nepakankamas mėginio tūris arba netinkami procedūriniai metodai yra labiausiai tikėtinos kontrolinės linijos neatsiradimo priežastys. Peržiūrėkite procedūrą ir pakartokite tyrimą su nauju testu. Jei problema išlieka, nedelsdami nutraukite tyrimo rinkinio naudojimą ir kreipkitės į vietinį platintoją.

【KOKYBĖS KONTROLĖ】

Teste yra integruota vidinė procedūrinė kontrolė. Kontrolinėje srityje (C) atsirandanti spalvota linija yra vidinė procedūrinė kontrolė. Ji patvirtina pakankamą mėginio tūrį, tinkamą membranos sudrėkinimą ir tinkamą procedūros techniką.

Kontrolinės standartinės medžiagos su šia testo kasete nepateikiamos, tačiau rekomenduojama atlikti teigiamų ir neigiamų kontrolinių mėginių tyrimus, nes tai yra gera laboratorinė praktika, kad būtų patvirtinta tyrimo procedūra ir patikrintas tinkamas tyrimo atlikimas.

【APRIBOJIMAI】

1. HIV 1.2 greitojo testo kasetė (bendras kraujas / serumas / plazma) yra skirta tik in vitro diagnostiniam naudojimui. Testas turi būti naudojamas ŽIV antikūnų nustatymui žmogaus bendrame kraujyje, serume arba plazmoje. Šiuo kokybiniu tyrimu negalima nustatyti nei kiekybinės vertės, nei ŽIV antikūnų koncentracijos.
2. HIV 1.2 greito testo kasetė (bendras kraujas / serumas / plazma) parodo tik ŽIV antikūnų buvimą mėginyje ir neturėtų būti naudojama kaip vienintelis ŽIV infekcijos diagnozavimo kriterijus.
3. Kaip ir atliekant visus diagnostinius tyrimus, visi rezultatai turi būti vertinami kartu su kita gydytojo turima klinikine informacija.
4. Jei tyrimo rezultatas neigiamas, o klinikiniai simptomai išlieka, rekomenduojama atlikti papildomus tyrimus kitais klinikiniais metodais. Neigiamas rezultatas neatmeta ŽIV infekcijos buvimo galimybės.

【TIKĖTINOS VERTĖS】

HIV 1.2 greitojo testo kasetė (bendras kraujas/serumas/plazma) buvo palyginta su rinkoje pirmaujančiu komerciniu EIA arba CMIA ŽIV rinkiniu. Šių dviejų sistemų koreliacija yra 99,9 %.

【VEIKSMINGUMO CHARAKTERISTIKOS】

Jautrumas ir specifiškumas

HIV 1.2 greitojo testo kasetė (bendras kraujas/serumas/plazma) teisingai identifikavo serokonversijos panelio mėginius ir buvo palyginta su pirmaujančiu komerciniu EIA ŽIV testu, kitu greituoju testu arba CMIA, naudojant klinikinius mėginius. Gauti rezultatai parodė, kad santykinis HIV 1.2 greito testo (bendras kraujas / serumas / plazma) kasetės jautrumas yra >99,9%, o santykinis specifiškumas yra 99,9%.

Metodas			IHI-402 greito testo kasetė (bendras kraujas / serumas / plazma)		Atitikimas
Numatytas tyrimas (EIA ar CIMA)	Rezultatas		Teigiamas	Neigiamas	
	Teigiamas	ŽIV-1	403	1	99,8% (403/404)
		ŽIV-2	100	0	>99,9% (100/100)
		Potipis	42	0	>99,9% (42/42)
		Iš viso	545	1	99,8% (545/546)
	Neigiamas	Kraujo donorų mėginiai	0	1000	>99,9% (1000/1000)
		Nėščių moterų mėginiai	0	200	>99,9% (200/200)
		Kliniškai neigiami	0	201	>99,9% (201/201)
		Iš viso	0	1401	>99,9% (1401/1401)
Bendras rezultatas			545	1402	99,9% (1946/1947)

Santykinis jautrumas: 99,8% (95%CI*: 99,0%~>99,9%);
Santykinis specifiškumas: 100% (95%CI*: 99,8%~100%);
Tikslumas: 99,9% (95%CI*: 99,7%~>99,99%) *Pasikliovimo intervalas

Preciziškumas

Tyrimo ribose

Preciziškumas tyrimo ribose buvo nustatomas naudojant 15 keturių mėginių kartotinių: neigiamą, silpnai teigiamą, vidutiniškai teigiamą ir stipriai teigiamą. Viena HIV 1.2 greitojo testo kasetės partija (bendras kraujas/serumas/plazma) buvo tiriama 10 dienų, naudojant neigiamus, silpnai teigiamus, vidutiniškai teigiamus ir stipriai teigiamus mėginius. >99% atvejų mėginiai buvo identifikuoti teisingai.

Tarp tyrimų

Preciziškumas tarp tyrimų buvo nustatomas atliekant 15 nepriklausomų tyrimų su tais

pačiais keturiais mėginiais: neigiamais, silpnai teigiamais, vidutiniškai teigiamais ir stipriai teigiamais. Trys skirtingos HIV 1.2 greitųjų testų kasečių partijos (bendras kraujas/serumas/plazma) buvo tirtos 3 dienas, naudojant neigiamus, silpnai teigiamus, vidutiniškai teigiamus ir stipriai teigiamus mėginius. >99% atvejų mėginiai buvo identifikuoti teisingai.

Kryžminis reaktyvumas

HIV 1.2 greito testo kasetė (bendras kraujas / serumas / plazma) buvo tirta su HBsAg, HBsAb, HBeAg, HBeAb, HBcAb, anti-Syphilis, anti-EBV, CEA, AFP, PSA, CA15-3, CA19-9, CA125, anti-HAV IgM, anti-HCV, anti-RF, anti-H.pylori, anti-CMV IgG, anti-Rubella IgG, anti-TOXO IgG, anti-HSV 1 IgG ir anti-HSV 2 IgG teigiamais mėginiais. Kryžminis reaktyvumas nebuvo stebimas.

Interferuojančios substancijos

Į ŽIV neigiamus ir teigiamus mėginius buvo pridėta šių galimai interferuojančių medžiagų.

Acetaminofenas: 20 mg/dl	Kofeinas: 20 mg/dl
Acetilsalicilo rūgštis: 20 mg/dl	Gentiso rūgštis: 20 mg/dl
Askorbo rūgštis: 2g/dl	Albuminas: 2 g/dl
Kreatinas: 200 mg/dl	Hemoglobinas: 1100mg/dl
Bilirubinas: 1 g/dl	Oksalo rūgštis: 600mg/dl

Nė viena iš tirtų medžiagų nurodytomis koncentracijomis neinterferavo tyrimo.

【LITERATŪROS NUORODOS】

1. Deeks, S., Overbaugh, J., Phillips, A. et al. HIV infection. Nat Rev Dis Primers 1, 15035 (2015). https://doi.org/10.1038/nrdp.2015.35
2. Salehi B, Kumar N V A, Şener B, et al. Medicinal plants used in the treatment of human immunodeficiency virus[J]. International journal of molecular sciences, 2018, 19(5): 1459.

Simbolių rodyklė

	Susipažinkite su naudojimo instrukcijomis arba elektroninėmis naudojimo instrukcijomis	Σ	Turinio pakanka <n> tyrimų	2°C 30°C	Temperatūros ribos
IVD	In vitro diagnostinė medicinos priemonė	LOT	Partijos kodas	REF	Katalogo numeris
EC REP	Įgaliotas atstovas Europos Bendrijoje		Naudokite iki nurodytos datos		Nenaudokite pakartotinai
	Nenaudokite, jei pakuotė pažeista, skaitykite naudojimo instrukcijas		Gamintojas		Dėmesio

Hangzhou AllTest Biotech Co.,Ltd.
#550,Yinhai Street
Hangzhou Economic & Technological Development Area
Hangzhou, 310018 P.R. China
Web: www.alltests.com.cn Email: info@alltests.com.cn

CE 2934

EC REP
MedNet EC-REP GmbH
Borkstrasse 10,
48163 Muenster,
Germany

Numeris: 146250100
Įsigaliojimo data: 2022-05-13

Tikslus dokumento vertimas į lietuvių kalbą
Vertėja Akvilė Gegelevičienė
Data 2022-10-12
UAB Diamedica
Gėlių g. 2, Avižieniai, Lietuva

SARS-CoV-2/Influenza A+B/RSV/Adenovirus Antigen Combo Rapid Test (Nasopharyngeal Swab) Package Insert

REF IRT-545	English

CE IVD

The SARS-CoV-2/Influenza A+B/RSV/Adenovirus Antigen Combo Rapid Test (Nasopharyngeal Swab) is a rapid chromatographic immunoassay for the qualitative detection of SARS-CoV-2 Nucleocapsid protein, Influenza A, Influenza B, Respiratory Syncytial Virus(RSV) and Adenovirus antigens present in human nasopharynx.
For professional in vitro diagnostic use only.

【INTENDED USE】

The SARS-CoV-2/Influenza A+B/RSV/Adenovirus Antigen Combo Rapid Test (Nasopharyngeal Swab) is a rapid chromatographic immunoassay for the qualitative detection of SARS-CoV-2 Nucleocapsid protein, Influenza A, Influenza B, Respiratory Syncytial Virus(RSV) and Adenovirus antigens in nasopharyngeal swab specimens from individuals with suspected SARS-CoV-2/Influenza/RSV/Adenovirus infection in conjunction with clinical presentation and the results of other laboratory tests.

Results are for the detection of SARS-CoV-2, Influenza A+B, RSV and Adenovirus antigens. An antigen is generally detectable in upper respiratory specimens during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out other bacterial/viral infection. The agent detected may not be the definite cause of disease.

Negative results do not preclude SARS-CoV-2/Influenza A+B/RSV/Adenovirus infection and should not be used as the sole basis for treatment or patient management decisions. Negative results should be treated as presumptive and confirmed with a molecular assay, if necessary for patient management. Negative results should be considered in the context of a patient's recent exposures, history and the presence of clinical signs and symptoms consistent with SARS-CoV-2, Influenza A+B, RSV and Adenovirus.

【SUMMARY】

The novel coronaviruses belong to the β genus. COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by the novel coronavirus are the main source of infection; asymptomatic infected people can also be an infectious source. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main manifestations include fever, fatigue and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases.

Influenza (commonly known as "flu") is a highly contagious, acute viral infection of the respiratory tract. It is a communicable disease easily transmitted through the coughing and sneezing of aerosolized droplets containing live virus. Laboratory identification of human influenza virus infections is commonly performed using direct antigen detection, virus isolation in cell culture, or detection of influenza-specific RNA by reverse transcriptase-polymerase chain reaction (RT-PCR). Rapid tests for influenza A and B virus infections, which can provide results within 30 minutes. [2]

Respiratory Syncytial Virus (RSV), which causes infection of the lungs and breathing passages, is a major cause of respiratory illness in young children. In adults, it may only produce symptoms of a common cold, such as a stuffy or runny nose, sore throat, mild headache, cough, fever, and a general feeling of being ill.Most children with RSV infection, both those who were hospitalized and those who were treated as outpatients, had no coexisting medical conditions or characteristics that significantly identified them as being at greater risk for severe RSV disease, except for being under 2 years of age. [3]

Human Adenoviruses comprise an important group of etiologic agents that are responsible for various diseases in adults and children, such as respiratory, ocular, gastroenteric, and urinary infections. In immunocompromised and organ-transplanted individuals, these agents can cause generalized infections. [4]

【PRINCIPLE】

The SARS-CoV-2 Antigen Rapid Test (Nasopharyngeal Swab) is a qualitative membrane-based immunoassay for the detection of SARS-CoV-2 Nucleocapsid protein in human nasopharyngeal swab specimen. SARS-CoV-2 antibody is coated in test line region. During testing, the specimen reacts with SARS-CoV-2 antibody-coated particles in the test. The mixture then migrates upward on the membrane by capillary action and reacts with the SARS-CoV-2 antibody in test line region. If the specimen contains SARS-CoV-2 Nucleocapsid protein, a colored line will appear in test line region as a result of this. If the specimen does not contain antigens to SARS-CoV-2, no colored line will appear in the test line region, indicating a negative result. To serve as a procedural control, a colored line will always appear in the control line region, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

The Influenza A+B Rapid Test (Nasopharyngeal Swab) is a qualitative, lateral flow immunoassay for the detection of Influenza A and Influenza B nucleoproteins in human nasopharyngeal swab specimen. In this test, antibody specific to the Influenza A and Influenza B nucleoproteins is separately coated on the test line regions of the test. During testing, the extracted specimen reacts with the antibody to Influenza A and/or Influenza B that are coated onto particles. The mixture migrates up the membrane to react with the antibody to Influenza A and/or Influenza B on the membrane and generate one or two colored lines in the test regions. The presence of this colored line in either or both of the test regions indicates a positive result. To serve as a procedural control, a colored line will always appear in the control region if the test has performed properly.

The RSV Rapid Test (Nasopharyngeal Swab) is a qualitative, lateral flow immunoassay for the detection of Respiratory Syncytial Virus nucleoproteins in nasopharyngeal swab specimens. In this test, antibody specific to the Respiratory Syncytial Virus nucleoproteins is coated on the test line region of the test. During testing, the extracted specimen reacts with the antibody to Respiratory Syncytial Virus that is coated onto particles. The mixture migrates up the membrane to react with the antibody to Respiratory Syncytial Virus on the membrane and generate one colored line in the test region. The presence of this colored line in the test region indicates a positive result. To serve as a procedural control, a colored line will always appear in the control region if the test has performed properly.

The Adenovirus Antigen Rapid Test (Nasopharyngeal Swab) is a qualitative membrane-based immunoassay for the detection of adenovirus antigen in nasopharyngeal swab specimens. In this test, antibody specific to the adenovirus is separately coated on the test line region of the test. During testing, the extracted specimen reacts with the antibody to adenovirus that are coated onto particles. The mixture migrates up the membrane to react with the antibody to adenovirus on the membrane and generate a color line in the test line region. The presence of this color line in the test line region indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a colored line will always appear in the control region if the test has performed properly.

【REAGENTS】

The test contains anti-SARS-CoV-2, anti-Influenza A, anti-Influenza B, anti-RSV and anti-Adenovirus as the capture reagent, anti-SARS-CoV-2, anti-Influenza A, anti-Influenza B, anti-RSV and anti-Adenovirus as the detection reagent.

【PRECAUTIONS】

1. This package insert must be read completely before performing the test. Failure to follow directions in package insert may yield inaccurate test results.
2. For professional *in vitro* diagnostic use only. Do not use after the expiration date.
3. Do not eat, drink or smoke in the area where the specimens or kits are handled.
4. Do not use test if pouch is damaged.
5. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout in the collection, handling, storage, and disposal of patient samples and used kit contents.
6. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
7. Viral Transport Media (VTM) may affect the test result, do not store specimens in viral transport media; extracted specimens for PCR tests cannot be used for the test.
8. Wash hands thoroughly after handling.
9. Please ensure that an appropriate amount of samples are used for testing. Too much or too little sample size may lead to deviation of results.
10. The used test should be discarded according to local regulations.
11. Humidity and temperature can adversely affect results.

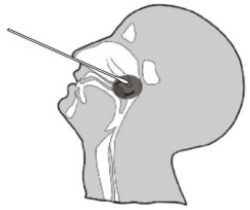
【STORAGE AND STABILITY】

Store as packaged in the sealed pouch at room temperature or refrigerated (2-30 °C). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

【SPECIMEN COLLECTION, TRANSPORT AND STORAGE】

Specimen Collection

1. Insert a sterile swab into the nostril of the patient, reaching the surface of the posterior nasopharynx.
2. Swab over the surface of the posterior nasopharynx 5-10 times.
3. Withdraw the sterile swab from the nasal cavity and avoid excess volume and highly-viscous nasopharyngeal discharge.



Specimen Transport and Storage

Specimens should be tested as soon as possible after collection. If swabs are not been processed immediately, it is highly recommended the swab specimen is placed into a dry, sterile and tightly sealed plastic tube for storage. The swab specimen in dry and sterile condition is stable for up to 24 hours at 2-8 °C.

【SPECIMEN PREPARATION】

Only the extraction buffer and tubes provided in the kit is to be used for swab specimen preparation.

Please refer to the Procedure Card for detailed information of Specimen Extraction.

1. Place the swab specimen in the Extraction Tube with Extraction Buffer. Rotate the swab for approximately 10 seconds while pressing the head against the inside of the tube to release the antigen in the swab.
2. Remove the swab while squeezing the swab head against the inside of the Extraction Tube as you remove it to expel as much liquid as possible from the swab. Discard the swab in accordance with your biohazard waste disposal protocol.

***NOTE**: The storage of the specimen after extraction is stable for 2 hours at room temperature or 24 hours at 2-8 °C.

【MATERIALS】

Materials provided

•Test Cassettes	•Package Insert	•Sterile Swabs
•Extraction Buffer	•Extraction Tubes and Tips (Optional)	•Workstation
•Procedure Card		

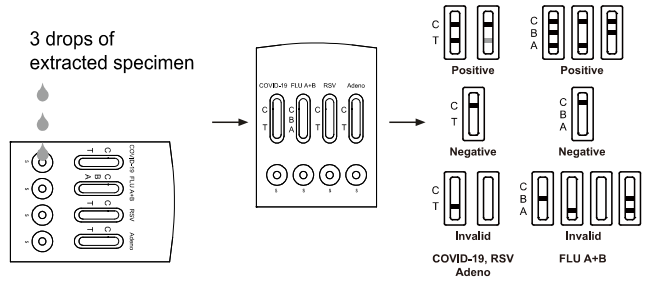
Materials required but not provided

• Timer

【DIRECTIONS FOR USE】

Allow the test, extracted specimen and/or controls to equilibrate to room temperature (15-30 °C) prior to testing.

1. Remove the test cassette from the sealed foil pouch and use it within one hour. Best results will be obtained if the test is performed immediately after opening the foil pouch.
2. Invert the specimen collection tube and add **3 drops of the extracted specimen** to each of the specimen well(S) respectively and then start the timer.
3. Wait for the colored line(s) to appear. **Read the result at 15 minutes**. Do not interpret the result after 20 minutes.



【INTERPRETATION OF RESULTS】

(Please refer to the illustration above)

SARS-CoV-2/RSV/Adenovirus POSITIVE:* Two colored lines appear in the SARS-CoV-2/RSV/Adenovirus window. One colored line should be in the control region (C) and another colored line should be in the test region (T). Positive result in the test region indicates detection of SARS-CoV-2/RSV/Adenovirus antigens in the specimen.

Influenza A POSITIVE:* Two colored lines appear in the FLU window. One colored line should be in the control region (C) and another colored line should be in the Influenza A region (A). Positive result in the Influenza A region indicates that Influenza A antigen was detected in the specimen.

Influenza B POSITIVE:* Two colored lines appear in the FLU window. One colored line should be in the control region (C) and another colored line should be in the Influenza B region (B). Positive result in the Influenza B region indicates that Influenza B antigen was detected in the specimen.

Influenza A and Influenza B POSITIVE:* Three colored lines appear in the FLU window. One colored line should be in the control region (C) and two colored line should be in the Influenza A region (A) and Influenza B region (B). Positive result in the Influenza A region and Influenza B region indicates that Influenza A antigen and Influenza B antigen were detected in the specimen.

***NOTE**: The intensity of the color in the test line region (T) will vary based on the amount of SARS-CoV-2 antigen, Influenza A and/or B antigen, RSV antigen, Adenovirus antigen present in the specimen. So any shade of color in the test region (T/B/A) should be considered positive.

NEGATIVE: One colored line appears in the control region (C). No apparent colored line appears in the test line region (T/B/A).

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

【QUALITY CONTROL】

Internal Quality Control

Internal procedural controls are included in the test. A colored line appearing in the control region (C) is an internal procedural control. It confirms sufficient specimen volume and correct procedural technique.

External Quality Control

Controls are not included in this kit. However, in compliance with Good Laboratory Practice (GLP) positive/negative controls are recommended.[1]

【LIMITATIONS】

1. The Test Procedure and the Interpretation of Test Result must be followed closely when testing for the presence of SARS-CoV-2/Influenza A/Influenza B/RSV/Adenovirus antigens in the human nasopharyngeal swab specimens from suspected individuals. For optimal test performance, proper specimen collection is critical. Failure to follow the procedure may give

inaccurate results.

2. The performance of the SARS-CoV-2/Influenza A+B/RSV/Adenovirus Antigen Combo Rapid Test (Nasopharyngeal Swab) was evaluated using the procedures provided in this product insert only. Modifications to these procedures may alter the performance of the test.
3. The SARS-CoV-2/Influenza A+B/RSV/Adenovirus Antigen Combo Rapid Test (Nasopharyngeal Swab) is for *in vitro* diagnostic use only. This test should be used for detection of SARS-CoV-2/Influenza A/Influenza B/RSV/Adenovirus Antigens in human nasopharyngeal swab specimens as an aid in the diagnosis of patients with suspected SARS-CoV-2, Influenza A, Influenza B, RSV or Adenovirus infection in conjunction with clinical presentation and the results of other laboratory tests. Neither the quantitative value nor the rate of increase in the concentration of SARS-CoV-2/Influenza A/Influenza B/RSV/Adenovirus antigens can be determined by this qualitative test.
4. The SARS-CoV-2/Influenza A+B/RSV/Adenovirus Antigen Combo Rapid Test (Nasopharyngeal Swab) will only indicate the presence of SARS-CoV-2/Influenza A/Influenza B/RSV/Adenovirus Antigens in the specimen and should not be used as the sole criteria for the diagnosis of SARS-CoV-2/Influenza A/Influenza B/RSV/Adenovirus infections.
5. The results obtained with the test should be considered with other clinical findings from other laboratory tests and evaluations.
6. If the test result is negative or non-reactive and clinical symptoms persist. It is recommended to re-sample the patient a few days later and test again or test with a molecular diagnostic device to rule out infection in these individuals.
7. The test will show negative results under the following conditions:
   a) The concentration of the novel coronavirus, influenza A virus, influenza B virus, RSV or Adenovirus antigens in the sample is lower than the minimum detection limit of the test.
   b) The optimal sampling time (peak virus concentration) after infection has not been verified, so collecting samples at different times for the same patient may avoid false negatives.
   c) Incorrect specimen collection and storage.
8. Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic should be considered to rule out infection in these individuals.
9. A negative result for Influenza A, Influenza B, RSV, Adenovirus obtained from this kit should be confirmed by RT-PCR/culture.
10. Positive results of SARS-CoV-2 may be due to infection with non-SARS-CoV-2 coronavirus strains or other interference factors. A positive result for influenza A and/or B, RSV and Adenovirus does not preclude an underlying co-infection with another pathogen, therefore the possibility of an underlying bacterial infection should be considered.

【PERFORMANCE CHARACTERISTICS】

Sensitivity, Specificity and Accuracy

The SARS-CoV-2/Influenza A+B/RSV/Adenovirus Antigen Combo Rapid Test (Nasopharyngeal Swab) has been evaluated with specimens obtained from the patients. RT-PCR is used as the reference method for the SARS-CoV-2/Influenza A+B/RSV/Adenovirus Antigen Combo Rapid Test (Nasopharyngeal Swab). Specimens were considered positive if RT-PCR indicated a positive result. Specimens were considered negative if RT-PCR indicated a negative result.

SARS-CoV-2 Test:

SARS-CoV-2/Influenza A+B/RSV/Adenovirus Antigen Combo Rapid Test		RT-PCR		Total
		Positive	Negative	
SARS-CoV-2 Antigen	Positive	80	2	82
	Negative	3	189	192
Total		83	191	274
Relative Sensitivity		96.4%（95%CI*: 89.8%~99.2%）		
Relative Specificity		99.0%（95%CI*: 96.3%~99.9%）		
Accuracy		98.2%（95%CI*: 95.8%~99.4%）		

Influenza A+B Test :

SARS-CoV-2/Influenza A+B/RSV/Adenovirus Antigen Combo Rapid Test		Type A			Type B		
		RT-PCR		Total	RT-PCR		Total
		Positive	Negative		Positive	Negative	
Flu A+B	Positive	38	2	40	39	2	41
	Negative	2	215	217	3	213	216
Total		40	217	257	42	215	257
Relative Sensitivity		95% (95%CI*: 82.6%-99.5%)			92.9% (95%CI*: 80.3%-98.2%)		
Relative Specificity		99.1% (95%CI*: 96.5%-99.9%)			99.1% (95%CI*: 96.5%-99.9%)		
Accuracy		98.4% (95%CI*: 95.9%-99.5%)			98.1% (95%CI*: 95.4%-99.3%)		

RSV Test:

SARS-CoV-2/Influenza A+B/RSV/Adenovirus Antigen Combo Rapid Test		RT-PCR		Total
		Positive	Negative	
RSV Antigen	Positive	33	9	42
	Negative	2	225	227
Total		35	234	269
Relative Sensitivity		94.3%(95%CI*:80.8%-99.3%)		
Relative Specificity		96.2%(95%CI*:92.8%-98.2%)		
Accuracy		95.9%(95%CI*:92.8%-97.9%)		

Adenovirus Test:

SARS-CoV-2/Influenza A+B/RSV/Adenovirus Antigen Combo Rapid Test		RT-PCR		Total
		Positive	Negative	
Adenovirus Antigen	Positive	31	3	34
	Negative	1	209	210
Total		32	212	244
Relative Sensitivity		96.9%(95%CI*:82.9%-99.9%)		
Relative Specificity		98.6%(95%CI*:95.7%-99.7%)		
Accuracy		98.4%(95%CI*:95.7%-99.5%)		

*Confidence Intervals

Specificity Testing with Various Viral Strains

The SARS-CoV-2/Influenza A+B/RSV/Adenovirus Antigen Combo Rapid Test (Nasopharyngeal Swab) was tested with the following viral strains. No discernible line at either of the test-line regions was observed at the concentrations listed:

Description	Concentration
Human coronavirus OC43	1 x 10^6 $TCID_{50}$/mL
Human coronavirus 229E	5 x 10^5 $TCID_{50}$/mL
Human coronavirus NL63	1 x 10^6 $TCID_{50}$/mL
Human coronavirus HKU1	1 x 10^6 $TCID_{50}$/mL
MERS COV Florida	1.17 x 10^4 $TCID_{50}$/mL
Human Rhinovirus 2	2.81 x 10^4 $TCID_{50}$/mL
Human Rhinovirus 14	1.58 x 10^6 $TCID_{50}$/mL
Human Rhinovirus 16	8.89 x 10^6 $TCID_{50}$/mL
Measles	1.58 x 10^4 $TCID_{50}$/mL
Mumps	1.58 x 10^4 $TCID_{50}$/mL
Parainfluenza virus 2	1.58 x 10^7 $TCID_{50}$/mL
Parainfluenza virus 3	1.58 x 10^8 $TCID_{50}$/mL

Precision

Intra-Assay&Inter-Assay

Within-run and Between-run precision has been determined by using below standard controls : Negative, SARS-CoV-2 antigen weak, SARS-CoV-2 antigen strong, Influenza A weak, Influenza B weak, Influenza A strong, Influenza B strong, RSV weak, RSV strong, Adenovirus weak and Adenovirus strong. Three different lots of SARS-CoV-2/Influenza A+B/RSV/Adenovirus Antigen Combo Rapid Test (Nasopharyngeal Swab) have been tested, ten replicates were tested with each standard control each day, and the test was conducted at 3 consecutive days. The specimens were correctly identified >99% of the time.

Cross-reactivity

The following organisms were tested at 1.0x10^8 org/mL and all found to be negative when tested with the SARS-CoV-2/Influenza A+B/RSV/Adenovirus Antigen Combo Rapid Test (Nasopharyngeal Swab):

Arcanobacterium	*Pseudomonas aeruginosa*
Candida albicans	*Staphylococcus aureus subspaureus*
Corynebacterium	*Staphylococcus epidermidis*
Escherichia coli	*Streptococcus pneumoniae*
Moraxella catarrhalis	*Streptococcus pyogenes*
Neisseria lactamica	*Streptococcus salivarius*
Neisseria subflava	*Streptococcus sp group F*

Interfering Substances

The interfering substances below were spiked with negative, SARS-CoV-2 antigen weak positive, Influenza A weak positive, Influenza B weak positive, RSV weak positive and Adenovirus weak positive. No substances showed any interference with the SARS-CoV-2/Influenza A+B/RSV/Adenovirus Antigen Combo Rapid Test (Nasopharyngeal Swab).

Substance	Concentration
Whole Blood	20 μl/mL
Mucin	50 μg/mL
Budesonide Nasal Spray	200 μl/mL
Dexamethasone	0.8 mg/mL
Flunisolide	6.8 ng/mL
Mupirocin	12 mg/mL
Oxymetazoline	0.6 mg/mL
Phenylephrine	12 mg/mL
Rebetol	4.5 μg/mL
Relenza	282 ng/mL
Tamiflu	1.1 μg/mL
Tobryamycin	2.43 mg/mL

【BIBLIOGRAPHY】

1. Westgard JO, Barry PL,HuntMR, Groth T. (1981). A multi-rule Shewhart for quality control in clinical chemistry, Clinical Chemistry. 27:493-501.
2. WHO recommendations on the use of rapid testing for influenza diagnosis, July 2005.
3. Caroline Breese Hall, M.D., Geoffrey A. Weinberg, M.D., Marika K. Iwane, Ph.D., et al. (2009). The Burden of Respiratory Syncytial Virus Infection in Young Children. N Engl J Med, 360(6): 588–598.
4. Inarei Paulini, Joselma Siqueira-Silva, Luciana Thomaz, et al. (2017) Development of a prototype immunochromatographic test for rapid diagnosis of respiratory adenovirus infection.The Brazilian Journal of Infectious Diseases.21(5): 500-506.

Index of Symbols

IVD	For *in vitro* diagnostic use only	Σ	Tests per kit	EC REP	Authorized Representative
2°C 30°C	Store between 2-30°C		Use by		Do not reuse
	Do not use if package is damaged	LOT	Lot Number	REF	Catalog #
	Manufacturer		Consult Instructions For Use		

Hangzhou AllTest Biotech Co.,Ltd.
#550,Yinhai Street,
Hangzhou Economic & Technological Development Area,
Hangzhou, Zhejiang, 310018 P.R. China
Web: www.alltests.com.cn
Email: info@alltests.com.cn

EC REP
Lotus NL B.V.
Koningin Julianaplein 10, 1e Verd, 2595AA,The Hague, Netherlands.
peter@lotusnl.com

Number: 146340002
Effective Date:2022-04-01

Strep A Rapid Test Cassette (Throat Swab) Package Insert

REF IST-502 | English

A rapid test for the qualitative detection of Strep A antigens in throat swab specimens.
For professional in vitro diagnostic use only.

【INTENDED USE】

The Strep A Rapid Test Cassette is a rapid chromatographic immunoassay for the qualitative detection of Strep A antigens from throat swab specimens to aid in the diagnosis of Group A Streptococcal infection.

【SUMMARY】

Streptococcus pyogenes is non-motile gram-positive cocci, which contains the Lancefield group A antigens that can cause serious infections such as pharyngitis, respiratory infection, impetigo, endocarditis, meningitis, puerperal sepsis, and arthritis.[1] Left untreated, these infections can lead to serious complications, including rheumatic fever and peritonsillar abscess.[2] Traditional identification procedures for Group A Streptococci infection involve the isolation and identification of viable organisms using techniques that require 24 to 48 hours or longer.[3,4]

The Strep A Rapid Test Cassette is a rapid test to qualitatively detect the presence of Strep A antigens in throat swab specimens, providing results within 5 minutes. The test utilizes antibodies specific for whole cell Lancefield Group A Streptococcus to selectively detect Strep A antigens in a throat swab specimen.

【PRINCIPLE】

The Strep A Rapid Test Cassette a qualitative, lateral flow immunoassay for the detection of Strep A carbohydrate antigen in a throat swab. In this test, antibody specific to Strep A carbohydrate antigen is coated on the test line region of the test. During testing, the extracted throat swab specimen reacts with an antibody to Strep A that is coated onto particles. The mixture migrates up the membrane to react with the antibody to Strep A on the membrane and generate a color line in the test line region. The presence of this color line in the test line region indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a colored line will always appear in the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

【REAGENT】

The test contains Strep A antibody coated particles and Strep A antibodies coated on the membrane.

【PRECAUTIONS】

1. For professional in vitro diagnostic use only. Do not use after the expiration date.
2. Do not eat, drink or smoke in the area where the specimens and kits are handled.
3. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow the standard procedures for proper disposal of specimens.
4. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
5. The used test should be discarded according to local regulations.
6. Humidity and temperature can adversely affect results.
7. Do not use test if pouch is damaged.
8. Reagent B contains an acidic solution. If the solution contacts the skin or eye, flush with large volumes of water.
9. The positive and negative controls contain sodium azide (Proclin300) as a preservative.
10. Do not interchange reagent bottle caps.
11. Do not interchange external control solution bottle caps.

【STORAGE AND STABILITY】

Store as packaged in the sealed pouch at room temperature or refrigerated (2-30°C). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

【SPECIMEN COLLECTION AND PREPARATION】

1. Collect the throat swab specimen with the sterile swab that is provided in the kit. Transport swabs containing modified Stuart's or Amies medium can also be used with this product. Swab the posterior pharynx, tonsils and other inflamed areas. Avoid touching the tongue, cheeks and teeth with the swab.[5]
2. Testing should be performed immediately after the specimens have been collected. Swab specimens may be stored in a clean, dry plastic tube for up to 8 hours at room temperature or 72 hours at 2-8°C.
3. If a culture is desired, lightly roll the swab tip onto a Group A selective (GAS) blood agar plate before using the swab in the Strep A Rapid Test Cassette

【MATERIALS】

Materials Provided

- Test Cassettes
- Extraction tubes
- Sterile swabs
- Workstation
- Dropper tips
- Package insert
- Extraction reagent 1 (2M NaNO2)
- Extraction reagent 2 (0.027M Citric acid)
- Positive control(Non-viable Strep A; 0.01% Proclin300)
- Negative control(Non-viable Strep C; 0.01% Proclin300)

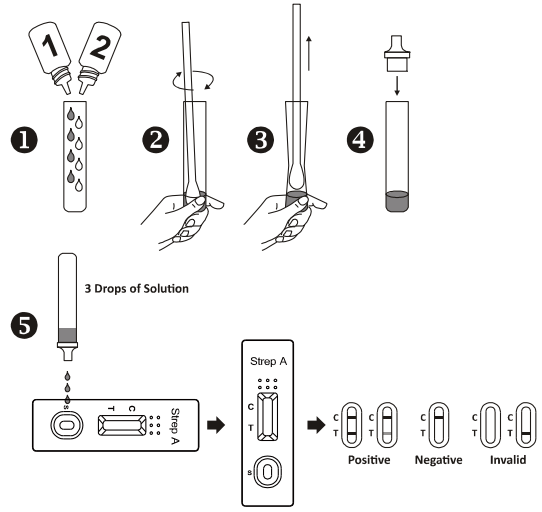
Materials Required But Not Provided

- Timer

【DIRECTIONS FOR USE】

Allow the test, reagents, throat swab specimen, and/or controls to reach room temperature (15-30℃) prior to testing.

1. Remove the test cassette from the sealed foil pouch and use it within one hour. Best results will be obtained if the test is performed immediately after opening the foil pouch.
2. Hold the Extraction Reagent 1 bottle vertically and add 4 full drops (approximately 240 µL) of Extraction Reagent 1 to an extraction tube. Extraction Reagent 1 is red in color. Hold the Extraction Reagent 2 bottle vertically and add 4 full drops (approximately 160 µL) to the tube. Extraction Reagent 2 is colorless. Mix the solution by gently swirling the extraction tube. The addition of Extraction Reagent 2 to Extraction Reagent 1 changes the color of the solution from red to yellow. See illustration 1.
3. Immediately add the swab into the extraction tube, agitate the swab vigorously 15 times, Leave the swab in the extraction test tube for **1 minute**. See illustration 2
4. Press the swab against the side of the tube and squeeze the bottom of the tube while removing the swab so that most of the liquid stays in the tube. Discard the swab. See illustration 3
5. Fit the dropper tip on top of the extraction tube. Place the test cassette on a clean and level surface. Add three drops of the solution (approx.100ul) to the sample well and then start the timer. Read the result at 5 minutes. Do not interpret the result after 10 minutes. See illustration 4 and illustration 5



【INTERPRETATION OF RESULTS】

(Please refer to the illustration above)

POSITIVE:* Two lines appear. One colored line should be in the control line region (C) and another apparent colored line should be in the test line region (T). A positive result indicates that Strep A was detected in the specimen.

***NOTE:** The intensity of the color in the test line region (T) will vary depending on the concentration of Strep A present in the specimen. Therefore, any shade of color in the test line region (T) should be considered positive.

NEGATIVE: One colored line appears in the control line region (C). No line appears in the test line region (T). A negative result indicates that Strep A antigen is not present in the specimen, or is present below the detectable level of the test. The patient's specimen should be cultured to confirm the absence of Strep A infection. If clinical symptoms are not consistent with results, obtain another specimen for culture.

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

【QUALITY CONTROL】

Internal Quality Control

Internal procedural controls are included in the test. A colored line appearing in the control region (C) is an internal positive procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

External Quality Control

It is recommended that a positive and negative external control be run every 25 tests, and as deemed necessary by internal laboratory procedures. External positive and negative controls are supplied in the kit. Alternatively, other Group A and non-Group A Streptococcus reference strains may be used as external controls. Some commercial controls may contain interfering preservatives; therefore, other commercial controls are not recommended.

Procedure for External Quality Control Testing

1. Add 4 full drops of Extraction Reagent 1 and 4 full drops of Extraction Reagent 2 into an extraction tube. Tap the bottom of the tube gently to mix the liquid.
2. Add 1 full drop of positive or negative control solution into the tube, holding the bottle upright.
3. Place a clean swab into this extraction tube and agitate the swab in the solution by rotating it at least 15 times. Leave the swab in the extraction tube for 1 minute. Then express the liquid from the swab head by rolling the swab against the inside of the extraction tube and squeezing the extraction tube as the swab is withdrawn. Discard the swab.
4. Continue with Step 5 of Directions For Use.
   If the controls do not yield the expected results, do not use the test results. Repeat the test or contact your distributor.

【LIMITATIONS】

1. The Strep A Rapid Test Cassette is for in vitro diagnostic use only. The test should be used for the detection of Strep A antigen in throat swab specimens only. Neither the quantitative value nor the rate of increase in Strep A antigen concentration can be determined by this qualitative test.
2. This test will only indicate the presence of Strep A antigen in the specimen from both viable and non-viable Group A Streptococcus bacteria.
3. A negative result should be confirmed by culture. A negative result may be obtained if the concentration of the Strep A antigen present in the throat swab is not adequate or is below the detectable level of the test.
4. Excess blood or mucus on the swab specimen may interfere with test performance and may yield a false positive result. Avoid touching the tongue, cheeks, and teeth[5] and any bleeding areas of the mouth with the swab when collecting specimens.
5. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.

【EXPECTED VALUES】

Approximately 15% of pharyngitis in children ages 3 months to 5 years is caused by Group A beta hemolytic Streptococcus.[6] In school-aged children and adults, the incidence of Strep throat infection is about 40%.[7] This disease usually occurs in the winter and early spring in temperate climates.[3]

【PERFORMANCE CHARACTERISTICS】

Sensitivity and Specificity

Using three medical centers for evaluation, a total of 526 throat swabs were collected from patients exhibiting symptoms of pharyngitis. Each swab was rolled onto a sheep blood agar plate, and then tested by the Strep A Rapid Test Cassette (Throat Swab). The plates were further streaked for isolation, and then incubated at 37℃ with 5-10% CO2 and a Bacitracin disk for 18-24 hours. The negative culture plates were incubated for an additional 18-24 hours. Possible GAS colonies were subcultured and confirmed with a commercially available latex agglutination grouping kit. Of the 526 total specimens, 404 were confirmed to be negative and 122 were confirmed to be positive by culture. During this study, one Strep F specimens yielded positive results with the Test. One of these specimens was re-cultured, then re-tested and yielded a negative result. Three additional different Strep F strains were cultured and tested for cross-reactivity and also yielded negative results.

Method		Culture		Total Results
Strep A Rapid Test Cassette	Results	Positive	Negative	
	Positive	116	9	125
	Negative	6	395	401
Total Results		122	404	526

Relative Sensitivity: 95.1% (95%CI*: 89.6%-98.2%) *Confidence Interval
Relative Specificity: 97.8% (95%CI*: 95.8%-99%)
Accuracy: 97.1% (95%CI*: 95.3%-98.4%)

Positive Culture Classification	Strep A Rapid Test/Culture	% Agreement
Rare	8/10	80.0%
1+	18/20	90.0%
2+	19/20	95.0%
3+	33/34	97.1%
4+	38/38	100.0%

Cross Reactivity

The following organisms were tested at 1.0 x 10^7 organisms per test and were all found to be negative when tested with the Strep A Rapid Test Cassette. No mucoid-producing strains were tested.

Group B Streptococcus	Neisseria meningitidis	Serratia marcescens
Group F Streptococcus	Neisseria sicca	Klebsiella pneumoniae
Streptococcus pneumoniae	Branhamella catarrhalis	Bordetella pertussis
Streptococcus mutans	Group C Streptococcus	Neisseria gonorrhea
Staphylococcus aureus	Group G Streptococcus	Neisseria subflava
Corynebacterium diphtheria	Streptococcus sanguis	Hemophilus influenza
Candida albicans	Staphylococcus epidermidis	Pseudomonas aeruginosa
Enterococcus faecalis		

【BIBLIOGRAPHY】

1. Murray, P.R., et al. Manual of Clinical Microbiology, 6th Edition, ASM Press, Washington D.C., 1995, p. 299-307.
2. Webb, KH. Does Culture Confirmation of High-sensitivity Rapid Streptococcal Tests Make Sense? A Medical Decision Analysis. Pediatrics (Feb 1998), 101:2, 2.
3. Bisno AL, Gerber MA, Gwaltney JM, Kaplan EL, Schwartz RH. Diagnosis and Management of Group A Streptococcal Pharyngitis. Clinical Infectious Diseases (1997), 25: 574-83.
4. Needham CA, McPherson KA, Webb KH. Streptococcal Pharyngitis: Impact of a High-sensitivity Antigen Test on Physician Outcome. Journal of Clinical Microbiology (Dec 1998), 36: 3468-3473.
5. Shea, Y.R., Specimen Collection and Transport, Clinical Microbiology Procedures Handbook, Isenberg, H.D., American Society of Microbiology, Washington D.C., 1.1.1-1.1.30, 1992.
6. Nussinovitch, M, Finkelstein Y, Amir J, Varsano, I. Group A beta-hemolytic streptococcal pharyngitis in preschool children aged 3 months to to 5 years. Clinical Pediatrics (June 1999), 38: 357-360.
7. Woods WA, Carter CT, Stack M, Connors Jr AF, Schlager TA. Group A Streptococcal Pharyngitis in Adults 30 to 65 years of age. Southern Medical Journal (May 1999), 491-492.

Index of Symbols

⚠	Attention, see instructions for use	Σ	Tests per kit	EC REP	Authorized Representative
IVD	For in vitro diagnostic use only	⏳	Use by	②	Do not reuse
2°C 30°C	Store between 2-30°C	LOT	Lot Number	REF	Catalog #
	Do not use if package is damaged				

Hangzhou AllTest Biotech Co., Ltd.
#550, Yinhai Street
Hangzhou Economic & Technological Development Area
Hangzhou - 310018, P. R. China
www.alltests.com.cn

EC REP
MedNet GmbH
Borkstrasse 10
48163 Muenster
Germany

Number: 145020004
Effective date: 2016-11-16

Multi-Drug Rapid Test Panel with Adulteration (Urine)

Package Insert

Instruction Sheet for testing of any combination of the following drugs:
ACE/AMP/BAR/BZO/BUP/COC/THC/MTD/MET/MDMA/MOP/MQL/OPI/PCP/PPX/TCA/TML/KET/OXY/COT/EDDP/FYL/K2/6-MAM/MDA/ETG/CLO/LSD/MPD/ZOL/MEP/ALC/MDPV/DIA/ZOP/MCAT/7-ACL/CFYL/CAF/CAT/TRO/ALP/ABP
Including Specimen Validity Tests (S.V.T.) for:
Oxidants/PCC, Specific Gravity, pH, Nitrite, Glutaraldehyde, Creatinine and Bleach

A rapid test for the simultaneous, qualitative detection of multiple drugs and drug metabolites in human urine. For healthcare professionals including professionals at point of care sites. Immunoassay for in vitro diagnostic use only.

【INTENDED USE】

The Multi-Drug Rapid Test Panel is a rapid chromatographic immunoassay for the qualitative detection of multiple drugs and drug metabolites in urine at the following cut-off concentrations:

Test	Calibrator	Cut-off (ng/mL)
Acetaminophen (ACE 5,000)	Acetaminophen	5,000
Amphetamine (AMP1,000)	d-Amphetamine	1,000
Amphetamine (AMP 500)	d-Amphetamine	500
Amphetamine (AMP 300)	d-Amphetamine	300
Barbiturates (BAR 300)	Secobarbital	300
Barbiturates (BAR 200)	Secobarbital	200
Benzodiazepines (BZO 500)	Oxazepam	500
Benzodiazepines (BZO 300)	Oxazepam	300
Benzodiazepines (BZO 200)	Oxazepam	200
Benzodiazepines (BZO 100)	Oxazepam	100
Buprenorphine (BUP 10)	Buprenorphine	10
Buprenorphine (BUP 5)	Buprenorphine	5
Cocaine (COC 300)	Benzoylecgonine	300
Cocaine (COC 200)	Benzoylecgonine	200
Cocaine (COC 150)	Benzoylecgonine	150
Cocaine (COC 100)	Benzoylecgonine	100
Marijuana (THC300)	11-nor-Δ9-THC-9 COOH	300
Marijuana (THC200)	11-nor-Δ9-THC-9 COOH	200
Marijuana (THC150)	11-nor-Δ9-THC-9 COOH	150
Marijuana (THC 50)	11-nor-Δ9-THC-9 COOH	50
Marijuana (THC 30)	11-nor-Δ9-THC-9 COOH	30
Marijuana (THC 25)	11-nor-Δ9-THC-9 COOH	25
Methadone (MTD 300)	Methadone	300
Methadone (MTD 200)	Methadone	200
Methamphetamine (MET 1,000)	d-Methamphetamine	1,000
Methamphetamine (MET 500)	d-Methamphetamine	500
Methamphetamine (MET 300)	d-Methamphetamine	300
Methylenedioxymethamphetamine (MDMA 300)	d,l-Methylenedioxymethamphetamine	300
Methylenedioxymethamphetamine (MDMA 500)	d,l-Methylenedioxymethamphetamine	500
Methylenedioxymethamphetamine (MDMA 1,000)	d,l-Methylenedioxymethamphetamine	1,000
Morphine (MOP 300)	Morphine	300
Morphine (MOP 200)	Morphine	200
Morphine (MOP 100)	Morphine	100
Methaqualone(MQL)	Methaqualone	300
Opiate (OPI 2,000)	Morphine	2,000
Phencyclidine (PCP)	Phencyclidine	25
Propoxyphene (PPX)	Propoxyphene	300
Tricyclic Antidepressants (TCA)	Nortriptyline	1,000
Tramadol (TML 100)	Cis-Tramadol	100
Tramadol (TML 200)	Cis-Tramadol	200
Tramadol (TML 300)	Cis-Tramadol	300
Ketamine (KET 1,000)	Ketamine	1,000
Ketamine (KET 500)	Ketamine	500
Ketamine (KET 300)	Ketamine	300
Ketamine (KET100)	Ketamine	100
Oxycodone (OXY)	Oxycodone	100
Cotinine(COT200)	Cotinine	200
Cotinine(COT100)	Cotinine	100
2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP300)	2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine	300
2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP100)	2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine	100
Fentanyl(FYL20)	Norfentanyl	20
Fentanyl(FYL10)	Norfentanyl	10
Synthetic Marijuana (K2-50)	JWH-018、JWH-073	50
Synthetic Marijuana (K2-30)	JWH-018、JWH-073	30
Synthetic Marijuana (K2-25)	JWH-018、JWH-073	25
6-mono-aceto-morphine (6-MAM10)	6-MAM	10
(±) 3,4-Methylenedioxy-Amphetamine(MDA500)	(±) 3,4-Methylenedioxy-Amphetamine	500
Ethyl- β-D-Glucuronide(ETG500)	Ethyl- β -D-Glucuronide	500
Ethyl- β-D-Glucuronide(ETG1,000)	Ethyl- β -D-Glucuronide	1,000
Clonazepam(CLO 400)	Clonazepam	400
Clonazepam(CLO 150)	Clonazepam	150
Lysergic Acid Diethylamide (LSD)	Lysergic Acid Diethylamide	20
Lysergic Acid Diethylamide (LSD)	Lysergic Acid Diethylamide	50
Methylphenidate (MPD)	Methylphenidate	300
Zolpidem(ZOL)	Zolpidem	50
Mephedrone	Mephedrone	100
3, 4-methylenedioxypyrovalerone (MDPV1000)	3, 4-methylenedioxypyrovalerone	1000
3, 4-methylenedioxypyrovalerone (MDPV 500)	3, 4-methylenedioxypyrovalerone	500
Diazepam(DIA 300)	Diazepam	300
Diazepam(DIA 200)	Diazepam	200
Zopiclone（ZOP 50）	Zopiclone	50
Methcathinone（MCAT 500）	S(-)-Methcathinone	500
7-Aminoclonazepam(7-ACL300)	7-Aminoclonazepam	300
7-Aminoclonazepam(7-ACL200)	7-Aminoclonazepam	200
7-Aminoclonazepam(7-ACL100)	7-Aminoclonazepam	100
Carfentanyl(CFYL500)	Carfentanyl	500
Caffeine(CAF)	Caffeine	1000
Cathine (CAT)	(+)-Norpseudoephedrine	150
Tropicamide(TRO)	Tropicamide	350
Alprazolam(ALP)	Alprazolam	100
AB-PINACA(ABP)	AB-PINACA	10

Test	Calibrator	Cut-off
Alcohol(ALC)	Alcohol	0.02%

Configurations of the Multi-Drug Rapid Test Panel come with any combination of the above listed drug analytes with or without S.V.T. This assay provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.

【SUMMARY】

The Multi-Drug Rapid Test Panel is a rapid urine screening test that can be performed without the use of an instrument. The test utilizes monoclonal antibodies to selectively detect elevated levels of specific drugs in urine.

【WHAT IS ADULTERATION】

Adulteration is the tampering of a urine specimen with the intention of altering the test results. The use of adulterants can cause false negative results in drug tests by either interfering with the screening test and/or destroying the drugs present in the urine. Dilution may also be employed in an attempt to produce false negative drug test results.

One of the best ways to test for adulteration or dilution is to determine certain urinary characteristics such as pH, specific gravity and creatinine and to detect the presence of oxidants/PCC, nitrites or glutaraldehyde in urine.

Oxidants/PCC (Pyridiniumchlorochromate)tests for the presence of oxidizing agents such as bleach and hydrogen peroxide. Pyridiniumchlorochromate (sold under the brand name Urine Luck) is a commonly used adulterant.8 Normal human urine should not contain oxidants of PCC.

Specific gravity tests for sample dilution. The normal range is from 1.003 to 1.030. Values outside this range may be the result of specimen dilution or adulteration.

Ph tests for the presence of acidic or alkaline adulterants in urine. Normal pH levels should be in the range of 4.0 to 9.0. Values outside of this range may indicate the sample has been altered.

Nitrite tests for commonly used commercial adulterants such as Klear and Whizzies. They work by oxidizing the major cannabinoid metabolite THC-COOH.9 Normal urine should contain no trace of nitrite. Positive results generally indicate the presence of an adulterant.

Glutaraldehyde tests for the presence of an aldehyde. Adulterants such as Urin Aid and Clear Choice contain glutaraldehyde which may cause false negative results by disrupting the enzyme used in some immunoassay tests.9 Glutaraldehyde is not normally found in urine; therefore, detection of glutaraldehyde in a urine specimen is generally an indicator of adulteration.

Creatinine is a waste product of creatine; an amino-acid contained in muscle tissue and found in urine.[2] A person may attempt to foil a test by drinking excessive amounts of water or diuretics such as herbal teas to " flush" the system. Creatinine and specific gravity are two ways to check for dilution and flushing, which are the most common mechanisms used in an attempt to circumvent drug testing. Low Creatinine and specific gravity levels may indicate dilute urine. The absence of Creatinine (<5 mg/dl) is indicative of a specimen not consistent with human urine.

Bleach tests for the presence of bleach bleach refers to a number of chemicals which remove color, whiten or disinfect, often by oxidation, Bleaches are used as household chemicals to whiten clothes and remove stains and as disinfectants. Normal human urine should not contain bleach.

【PRINCIPLE (FOR DOA TESTS EXCLUDING ALCOHOL)】

During testing, a urine specimen migrates upward by capillary action. A drug, if present in the urine specimen below its cut-off concentration, will not saturate the binding sites of its specific antibody. The antibody will then react with the drug-protein conjugate and a visible colored line will show up in the test region of the specific drug dipstick. The presence of drug above the cut-off concentration will saturate all the binding sites of the antibody. Therefore, the colored line will not form in the test region.

A drug-positive urine specimen will not generate a colored line in the specific test region of the dipstick because of drug competition, while a drug-negative urine specimen will generate a line in the test region because of the absence of drug competition.

To serve as a procedural control, a colored line will always appear at the control region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

【PRINCIPLE (FOR ALCOHOL)】

The urine Alcohol Rapid Test consists of a plastic strip with a reaction pad attached at the tip. On contact with alcohol, the reaction pad will change colors depending on the concentration of alcohol present. This is based on the high specificity of alcohol oxidase for ethyl alcohol in the presence of peroxidase and enzyme substrate such as TMB.

【REAGENTS(FOR DOA TESTS EXCLUDING ALCOHOL)】

Each test line contains anti-drug mouse monoclonal antibody and corresponding drug-protein conjugates. The control line contains goat anti-rabbit IgG polyclonal antibodies and rabbit IgG.

【REAGENTS (FOR ALCOHOL)】

Tetramethylbenzidine,
Alcohol Oxidase
Peroxidase

【S.V.T REAGENTS】

Adulteration Pad	Reactive indicator	Buffers and non-reactive ingredients
Creatinine	0.04%	99.95%
Nitrite	0.07%	99.94%
Bleach	0.39%	99.77%
Glutaraldehyde	0.02%	99.97%
pH	0.06%	99.94%
Specific Gravity	0.25%	99.78%
Oxidants / PCC	0.36%	99.70%

【PRECAUTIONS】

- For healthcare professionals including professionals at point of care sites.
- Immunoassay for *in vitro* diagnostic use only. The test Panel should remain in the sealed pouch until use.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The used test Panel should be discarded according to federal, state and local regulations.

【STORAGE AND STABILITY】

Store as packaged in the sealed pouch at 2-30°C. The test is stable through the expiration date printed on the sealed pouch. The test Panels must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

【SPECIMEN COLLECTION AND PREPARATION】

Urine Assay

The urine specimen should be collected in a clean and dry container. Urine collected at any time of the day may be used. Urine specimens exhibiting visible precipitates should be centrifuged, filtered, or allowed to settle to obtain a clear specimen for testing.

Specimen Storage

Urine specimens may be stored at 2-8°C for up to 48 hours prior to testing. For prolonged storage, specimens may be frozen and stored below -20°C. Frozen specimens should be thawed and mixed well before testing. When testing cards with S.V.T. or Alcohol storage of urine specimens should not exceed 2 hours at room temperature or 4 hours refrigerated prior to testing.

【MATERIALS】

Materials Provided

- Test Panels
- Package insert
- Adulteration Color Chart (when applicable)

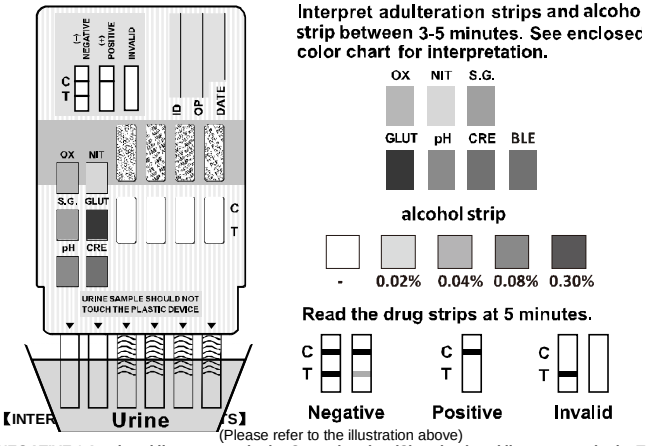
Materials Required But Not Provided

- timer

【DIRECTIONS FOR USE】

Allow the test, urine specimen, and/or controls to reach room temperature (15-30ºC) prior to testing.

1. Bring the pouch to room temperature before opening it. Remove the test panel from the sealed pouch and use it within one hour.
2. Remove the cap.
3. With the arrow pointing toward the urine specimen, immerse the test panel vertically in the urine specimen for at least 10 to 15 seconds. **Immerse the dipstick to at least the level of the wavy lines, but not above the arrow on the test panel.**
4. Replace the cap and place the test panel on a non-absorbent flat surface.
5. Start the timer and wait for the colored line(s) to appear.
6. Read the adulteration strips and Alcohol strip between 3-5 minutes according to color chart provided separately/on foil pouch. Refer to your Drug Free Policy for guidelines on adulterated specimens. We recommend not to interpret the drug test results and either retest the urine or collect another specimen in case of any positive result for any adulteration test.
7. The drug strip result should be read at 5 minutes. Do not interpret the result after 10 minutes.



【INTER S】(Please refer to the illustration above)

NEGATIVE:* A colored line appears in the Control region (C) and colored lines appear in the Test region (T). This negative result means that the concentrations in the urine sample are below the designated cut-off levels for a particular drug tested.

***NOTE:** The shade of the colored lines(s) in the Test region (T) may vary. The result should be considered negative whenever there is even a faint line.

POSITIVE: A colored line appears in the Control region (C) and NO line appears in the Test region (T). The positive result means that the drug concentration in the urine sample is greater than the designated cut-off for a specific drug.

INVALID: No line appears in the Control region (C). Insufficient specimen volume or incorrect

procedural techniques are the most likely reasons for Control line failure. Read the directions again and repeat the test with a new test card. If the result is still invalid, contact your manufacturer.

【INTERPRETATION OF RESULTS (S.V.T/ ADULTERATION)】

(Please refer to the color chart)

Semi Quantitative results are obtained by visually comparing the reacted color blocks on the strip to the printed color blocks on the color chart.

No instrumentation is required.

【INTERPRETATION OF RESULTS (ALCOHOL STRIP)】

Negative: Almost no color change by comparing with the background. The negative result indicates that the urine alcohol level is less than 0.02%.

Positive: A distinct color developed all over the pad. The positive result indicates that the urine alcohol concentration is 0.02% or higher.

Invalid: The test should be considered invalid If only the edge of the reactive pad turned color that might be ascribed to insufficient sampling. The subject should be re-tested. Besides, if the color pad has a blue color before applying urine sample, do not use the test.

【QUALITY CONTROL】

A procedural control is included in the test. A line appearing in the control region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

Control standards are not supplied with this kit. However, it is recommended that positive and negative controls be tested as good laboratory practice to confirm the test procedure and to verify proper test performance.

【LIMITATIONS】

1. The Multi-Drug Rapid Test Panel provides only a qualitative, preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method.[1-10]
2. There is a possibility that technical or procedural errors, as well as interfering substances in the urine specimen may cause erroneous results.
3. Adulterants, such as bleach and/or alum, in urine specimens may produce erroneous results regardless of the analytical method used. If adulteration is suspected, the test should be repeated with another urine specimen.
4. A positive result does not indicate level or intoxication, administration route or concentration in urine.
5. A negative result may not necessarily indicate drug-free urine. Negative results can be obtained when drug is present but below the cut-off level of the test.
6. This test does not distinguish between drugs of abuse and certain medications.
7. A positive test result may be obtained from certain foods or food supplements. Alcohol in the atmosphere, such as spray from perfumes, deodorizers, glass cleaners etc. can affect the Alcohol Rapid Tests. Therefore, adequate measures should be taken to avoid undue interference from such atmospheric agents in the testing area.
8. The test is only for detection of presence/ absence of alcohol in the urine, which may result from habitual drinking or medications and does not discriminate the two.

【S.V.T/ ADULTERATION LIMITATIONS】

1. The adulteration tests included with the product are meant to aid in the determination of abnormal specimens. While comprehensive, these tests are not meant to be an “all-inclusive” representation of possible adulterants.
2. Oxidants/PCC: Normal human urine should not contain oxidants or PCC. The presence of high levels of antioxidants in the specimen, such as ascorbic acid, may result in false negative results for the oxidants/PCC pad.
3. Specific Gravity: Elevated levels of protein in urine may cause abnormally high specific gravity values.
4. Nitrite: Nitrite is not a normal component of human urine. However, nitrite found in urine may indicate urinary tract infections or bacterial infections. Nitrite levels of > 20 mg/dL may produce false positive glutaraldehyde results.
5. Glutaraldehyde: is not normally found in urine. However certain metabolic abnormalities such as ketoacidosis (fasting, uncontrolled diabetes or high protein diets) may interfere with the test results.
6. Creatinine: Normal Creatinine levels are between 20 and 350 mg/dL. Under rare conditions, certain kidney diseases may show dilute urine.
7. Bleach: Normal human urine should not contain bleach. The presence of high levels of bleach in the specimen may result in false negative results for the bleach pad.

【EXPECTED VALUES】

The negative result indicates that the drug concentration is below the detectable level. Positive result means the concentration of drug is above the detectable level.

【PERFORMANCE CHARACTERISTICS】

Accuracy

A side-by-side comparison was conducted using the Multi-Drug Rapid Test Panel and commercially available drug rapid tests. Testing was performed on approximately 250 specimens per drug type previously collected from subjects presenting for Drug Screen Testing. Presumptive positive results were confirmed by GC/MS.

Method		GC/MS		% agreement with GC/MS
Multi-Drug Rapid Test Panel		Positive	Negative	
ACE 5,000	Positive	29	1	93.5%
	Negative	2	68	98.6%
AMP 1,000	Positive	103	3	98.1%
	Negative	2	142	97.9%
AMP 500	Positive	110	2	99.1%
	Negative	1	137	98.6%
AMP 300	Positive	116	2	99.1%
	Negative	1	131	98.5%
BAR 300	Positive	98	2	96.1%
	Negative	4	146	98.6%
BAR 200	Positive	101	3	95.3%
	Negative	5	141	97.9%
BZO 500	Positive	112	3	98.2%
	Negative	2	133	97.8%
BZO 300	Positive	121	1	98.4%
	Negative	2	126	99.2%
BZO 200	Positive	127	2	99.2%
	Negative	1	120	98.4%
BZO 100	Positive	128	3	99.2%
	Negative	1	118	97.5%
BUP 10	Positive	105	0	99.1%
	Negative	1	144	>99.9%
BUP 5	Positive	105	0	99.1%
	Negative	1	144	>99.9%
COC 300	Positive	111	3	98.2%
	Negative	2	134	97.8%
COC 200	Positive	40	0	>99.9%
	Negative	0	60	>99.9%
COC 150	Positive	116	4	98.3%
	Negative	2	128	97.0%
COC 100	Positive	117	4	99.2%
	Negative	1	128	97.0%
THC 300	Positive	85	3	95.5%
	Negative	4	158	98.1%
THC 200	Positive	85	4	93.4%
	Negative	6	155	97.5%
THC 150	Positive	86	4	94.5%
	Negative	5	155	97.5%
THC 50	Positive	92	3	97.9%
	Negative	2	153	98.1%
THC 30	Positive	94	3	97.9%
	Negative	2	151	98.1%
THC 25	Positive	95	4	96.9%
	Negative	3	148	97.4%
MTD 300	Positive	89	2	98.9%
	Negative	1	158	98.8%
MTD 200	Positive	91	2	98.7%
	Negative	1	156	98.7%
MET 1,000	Positive	76	5	96.2%
	Negative	3	166	97.1%
MET 500	Positive	83	5	97.6%
	Negative	2	160	97.0%
MET 300	Positive	88	4	97.8%
	Negative	2	156	97.5%
MDMA 1,000	Positive	99	1	98.0%
	Negative	2	148	99.3%
MDMA 500	Positive	102	1	98.1%
	Negative	2	145	99.3%
MDMA 300	Positive	103	1	98.1%
	Negative	2	144	99.3%
MOP 300	Positive	95	7	95.0%
	Negative	5	143	95.3%
MOP 200	Positive	95	6	95.0%
	Negative	5	144	96.0%
MOP 100	Positive	98	5	97.0%
	Negative	3	144	96.6%
MQL	Positive	79	11	89.8%
	Negative	9	151	93.2%
OPI	Positive	117	8	96.7%
	Negative	4	121	93.8%
PCP	Positive	85	5	92.4%
	Negative	7	153	96.8%
PPX	Positive	97	9	96.0%
	Negative	4	140	94.0%
TCA	Positive	91	13	94.8%
	Negative	5	141	91.6%
TML 100	Positive	82	12	88.2%
	Negative	11	145	92.4%
TML 200	Positive	82	6	88.2%
	Negative	11	151	96.2%
TML 300	Positive	81	6	88.0%
	Negative	11	152	96.2%
KET 1,000	Positive	77	3	97.5%
	Negative	2	168	98.2%
KET 500	Positive	81	3	97.6%
	Negative	2	164	98.2%
KET 300	Positive	89	4	96.7%
	Negative	3	154	97.5%
KET 100	Positive	97	4	96.0%
	Negative	4	145	97.3%
OXY 100	Positive	84	1	97.7%
	Negative	2	163	99.4%
COT 200	Positive	88	4	96.7%
	Negative	3	155	97.5%
COT 100	Positive	93	3	97.9%
	Negative	2	152	98.1%
EDDP 300	Positive	92	1	97.9%
	Negative	2	155	99.4%
EDDP 100	Positive	95	5	96.9%
	Negative	3	147	96.7%
FYL 20	Positive	79	1	98.8%
	Negative	1	169	99.4%
FYL 10	Positive	80	1	98.8%
	Negative	1	168	99.4%
K2-50	Positive	78	3	97.5%
	Negative	2	167	98.2%
K2-30	Positive	82	2	97.6%
	Negative	2	164	98.8%
K2-25	Positive	82	3	97.6%
	Negative	2	163	98.2%
6-MAM10	Positive	42	2	97.7%
	Negative	1	105	98.1%
MDA500	Positive	103	3	98.1%
	Negative	2	142	97.9%
ETG500	Positive	83	1	97.6%
	Negative	2	164	99.4%
ETG1,000	Positive	81	1	95.3%
	Negative	4	164	99.4%
CLO 400	Positive	101	1	97.1%
	Negative	3	145	99.3%
CLO 150	Positive	103	2	99.0%
	Negative	1	144	98.6%
LSD 20	Positive	33	1	94.3%
	Negative	2	64	98.5%
LSD 50	Positive	32	1	94.1%
	Negative	2	65	98.5%
MPD	Positive	35	1	94.6%
	Negative	2	62	98.4%
ZOL	Positive	20	2	90.9%
	Negative	2	66	97.1%
MEP100	Positive	19	2	90.5%
	Negative	2	64	97.0%
MDPV1000	Positive	28	1	93.3%
	Negative	2	69	98.6%
MDPV 500	Positive	27	1	93.1%
	Negative	2	59	98.3%
DIA 300	Positive	121	1	98.4%
	Negative	2	126	99.2%
DIA 200	Positive	121	1	98.4%
	Negative	2	126	99.2%
ZOP 50	Positive	19	2	86.4%
	Negative	3	69	97.2%
MCAT 500	Positive	20	4	90.9%
	Negative	2	76	95.0%
7-ACL 300	Positive	32	1	94.1%
	Negative	2	43	97.7%
7-ACL 200	Positive	35	1	94.6%
	Negative	2	40	97.6%
7-ACL 100	Positive	36	1	94.7%
	Negative	2	39	97.5%
CFYL 500	Positive	36	1	94.7%
	Negative	2	72	98.6%
CAF 1000	Positive	21	3	91.3%
	Negative	2	66	95.7%
CAT 150	Positive	19	2	90.5%
	Negative	2	73	97.3%
TRO 350	Positive	23	2	92.0%
	Negative	2	64	97.0%
ALP 100	Positive	20	2	90.9%
	Negative	2	74	97.4%
ABP 10	Positive	23	2	92.0%
	Negative	2	68	97.1%

% Agreement with Commercial Kit

	ACE 5,000	AMP 1,000	AMP 500	AMP 300	BAR 300	BAR 200	BZO 500	BZO 300	BZO 200	BZO 100	BUP 10
Positive Agreement	*	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%
Negative Agreement	*	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%
Total Results	*	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%

	BUP 5	COC 300	COC 200	COC 150	COC 100	THC 150	THC 50	THC 25	MTD 300	MTD 200	MET 1,000
Positive Agreement	*	>99.9%	*	*	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%
Negative Agreement	*	>99.9%	*	*	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%
Total Results	*	>99.9%	*	*	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%

	MET 500	MET 300	MDMA 1,000	MDMA 500	MDMA 300	MOP 300	MOP 100	MQL	OPI	PCP	PPX
Positive Agreement	>99.9%	>99.9%	>99.9%	>99.9%	*	>99.9%	>99.9%	>99.9%	*	>99.9%	>99.9%
Negative Agreement	>99.9%	>99.9%	>99.9%	>99.9%	*	>99.9%	>99.9%	>99.9%	*	>99.9%	>99.9%
Total Results	>99.9%	>99.9%	>99.9%	>99.9%	*	>99.9%	>99.9%	>99.9%	*	>99.9%	>99.9%

	TCA	TML 100	TML 200	TML 300	KET 1,000	KET 500	KET 300	KET 100	OXY	COT 200	COT 100
Positive Agreement	*	*	*	*	>99.9%	>99.9%	>99.9%	>99.9%	*	*	*
Negative Agreement	*	*	*	*	>99.9%	>99.9%	>99.9%	>99.9%	*	*	*
Total Results	*	*	*	*	>99.9%	>99.9%	>99.9%	>99.9%	*	*	*

	EDDP 300	EDDP 100	FYL 20	FYL 10	K2 50	K2 30	K5 25	6-MAM 10	MDA 500	ETG 500	ETG 1,000	CLO 400
Positive Agreement	*	*	*	*	*	*	*	*	*	*	*	*
Negative Agreement	*	*	*	*	*	*	*	*	*	*	*	*
Total Results	*	*	*	*	*	*	*	*	*	*	*	*

	CLO 150	LSD 20	LSD 50	MPD	ZOL	THC 200	THC 30/30 0	MOP 200	MEP 100	MDP V 1000	DIA 300	DIA 200	ZOP 50	MCA T 500
Positive Agreement	*	*	*	*	*	>99.9 %	*	*	*	*	*	*	*	*
Negative Agreement	*	*	*	*	*	>99.9 %	*	*	*	*	*	*	*	*
Total Results	*	*	*	*	*	>99.9 %	*	*	*	*	*	*	*	*

	7-ACL 300	7-ACL 200	7-ACL 100	CFYL 500	CAF 1000	CAT 150	TRO 350	ALP	MDPV 500	ABP 10
Positive Agreement	*	*	*	*	*	*	*	*	*	*
Negative Agreement	*	*	*	*	*	*	*	*	*	*
Total Results	*	*	*	*	*	*	*	*	*	*

* Note: Based on GC/MS data instead of Commercial Kit.

Precision

A study was conducted at three hospitals by laypersons using three different lots of product to demonstrate the within run, between run and between operator precision. An identical card of coded specimens, containing drugs at concentrations of ± 50% and ± 25% cut-off level, was labeled, blinded and tested at each site. The results are given below:

ACETAMINOPHEN (ACE5,000)

Amphetamine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
2,500	10	10	0	10	0	10	0
3,750	10	9	1	9	1	8	2
6,250	10	1	9	1	9	1	9
7,500	10	0	10	0	10	0	10

AMPHETAMINE (AMP 1,000)

Amphetamine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
500	10	10	0	10	0	10	0
750	10	9	1	8	2	9	1
1,250	10	1	9	2	8	2	8
1,500	10	0	10	0	10	0	10

AMPHETAMINE (AMP 500)

Amphetamine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
250	10	10	0	10	0	10	0
375	10	9	1	9	1	9	1
625	10	2	8	1	9	2	8
750	10	0	10	0	10	0	10

AMPHETAMINE (AMP 300)

Amphetamine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
150	10	10	0	10	0	10	0
225	10	8	2	8	2	8	2
375	10	2	8	2	8	2	8
450	10	0	10	0	10	0	10

BARBITURATES (BAR 300)

Secobarbital conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
150	10	10	0	10	0	10	0
225	10	9	1	8	2	9	1
375	10	2	8	1	9	2	8
450	10	0	10	0	10	0	10

BARBITURATES (BAR 200)

Secobarbital	n per	Site A		Site B		Site C	

conc. (ng/mL)	site	-	+	-	+	-	+
0	10	10	0	10	0	10	0
100	10	10	0	10	0	10	0
150	10	9	1	9	1	9	1
250	10	1	9	1	9	1	9
300	10	0	10	0	10	0	10

BENZODIAZEPINES (BZO 500)

Oxazepam conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
250	10	10	0	10	0	10	0
375	10	8	2	9	1	8	2
625	10	1	9	2	8	1	9
750	10	0	10	0	10	0	10

BENZODIAZEPINES (BZO 300)

Oxazepam conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
150	10	10	0	10	0	10	0
225	10	9	1	9	1	9	1
375	10	1	9	1	9	1	9
450	10	0	10	0	10	0	10

BENZODIAZEPINES (BZO 200)

Oxazepam conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
100	10	10	0	10	0	10	0
150	10	9	1	8	2	9	1
250	10	1	9	1	9	2	8
300	10	0	10	0	10	0	10

BENZODIAZEPINES (BZO 100)

Oxazepam conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
50	10	10	0	10	0	10	0
75	10	9	1	8	2	7	3
125	10	1	9	1	9	2	8
150	10	0	10	0	10	0	10

BUPRENORPHINE (BUP 10)

Buprenorphine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
5	10	10	0	10	0	10	0
7.5	10	9	1	9	1	8	2
12.5	10	1	9	1	9	1	9
15	10	0	10	0	10	0	10

BUPRENORPHINE (BUP 5)

Buprenorphine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
2.5	10	10	0	10	0	10	0
3.75	10	9	1	9	1	8	2
6.25	10	1	9	1	9	1	9
7.5	10	0	10	0	10	0	10

COCAINE (COC 300)

Benzoylecgonine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
150	10	10	0	10	0	10	0
225	10	9	1	9	1	9	1
375	10	1	9	1	9	1	9
450	10	0	10	0	10	0	10

COCAINE (COC 200)

Benzoylecgonine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
100	10	10	0	10	0	10	0
150	10	9	1	9	1	9	1
250	10	1	9	1	9	1	9
300	10	0	10	0	10	0	10

COCAINE (COC 150)

Benzoylecgonine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
75	10	10	0	10	0	10	0

112.5	10	9	1	9	1	9	1
187.5	10	2	8	2	8	2	8
225	10	0	10	0	10	0	10

COCAINE (COC 100)

Benzoylecgonine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
50	10	10	0	10	0	10	0
75	10	9	1	9	1	9	1
125	10	2	8	2	8	2	8
150	10	0	10	0	10	0	10

MARIJUANA (THC300)

11-nor-Δ9-THC-9 COOH Concentration (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
150	10	10	0	10	0	10	0
225	10	8	2	9	1	9	1
375	10	2	8	3	7	1	9
450	10	0	10	0	10	0	10

MARIJUANA (THC200)

11-nor-Δ^9-COOH conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
100	10	10	0	10	0	10	0
150	10	9	1	9	1	9	1
250	10	2	8	1	9	1	9
300	10	0	10	0	10	0	10

MARIJUANA (THC150)

11-nor-Δ^9-COOH conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
75	10	10	0	10	0	10	0
112.5	10	9	1	9	1	9	1
187.5	10	2	8	1	9	1	9
225	10	0	10	0	10	0	10

MARIJUANA (THC50)

11-nor-Δ^9-COOH conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
25	10	10	0	10	0	10	0
37.5	10	9	1	8	2	9	1
62.5	10	1	9	1	9	2	8
75	10	0	10	0	10	0	10

MARIJUANA (THC25)

11-nor-Δ^9-COOH conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
12.5	10	10	0	10	0	10	0
18.75	10	8	2	8	2	8	2
31.25	10	1	9	1	9	2	8
37.5	10	0	10	0	10	0	10

MARIJUANA (THC30)

11-nor-Δ^9-COOH conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	-	+	-
0	10	10	0	10	0	10	0
15	10	10	0	10	0	10	0
22.5	10	9	1	9	1	9	1
37.5	10	2	8	2	8	1	9
45	10	0	10	0	10	0	10

METHADONE (MTD300)

Methadone conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
150	10	10	0	10	0	10	0
225	10	9	1	9	1	9	1
375	10	1	9	1	9	1	9
450	10	0	10	0	10	0	10

METHADONE (MTD200)

Methadone conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
100	10	10	0	10	0	10	0
150	10	8	2	8	2	8	2
250	10	1	9	1	9	2	8
300	10	0	10	0	10	0	10

METHAMPHETAMINE (MET1,000)

Methamphetamine	n per	Site A		Site B		Site C	

conc. (ng/mL)	site	-	+	-	+	-	+
0	10	10	0	10	0	10	0
500	10	10	0	10	0	10	0
750	10	9	1	9	1	9	1
1,250	10	1	9	2	8	1	9
1,500	10	0	10	0	10	0	10

METHAMPHETAMINE (MET 500)

Methamphetamine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
250	10	10	0	10	0	10	0
375	10	9	1	9	1	9	1
625	10	1	9	1	9	1	9
750	10	0	10	0	10	0	10

METHAMPHETAMINE (MET300)

Methamphetamine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
150	10	10	0	10	0	10	0
225	10	9	1	9	1	9	1
375	10	1	9	1	9	1	9
450	10	0	10	0	10	0	10

METHYLENEDIOXYMETHAMPHETAMINE (MDMA1, 000) Ecstasy

Methylenedioxymethamphetamine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
500	10	10	0	10	0	10	0
750	10	9	1	9	1	8	2
1,250	10	1	9	1	9	1	9
1,500	10	0	10	0	10	0	10

METHYLENEDIOXYMETHAMPHETAMINE (MDMA 500) Ecstasy

Methylenedioxymethamphetamine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
250	10	10	0	10	0	10	0
375	10	8	2	9	1	9	1
625	10	1	9	1	9	1	9
750	10	0	10	0	10	0	10

METHYLENEDIOXYMETHAMPHETAMINE (MDMA 300) Ecstasy

Methylenedioxymethamphetamine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
250	10	10	0	10	0	10	0
375	10	8	2	9	1	7	3
625	10	2	8	1	9	1	9
750	10	0	10	0	10	0	10

MORPHINE (MOP 300)

Morphine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
150	10	10	0	10	0	10	0
225	10	9	1	9	1	9	1
375	10	1	9	1	9	1	9
450	10	0	10	0	10	0	10

MORPHINE (MOP 200)

Morphine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
100	10	10	0	10	0	10	0
150	10	7	3	9	1	9	1
250	10	1	9	2	8	1	9
300	10	0	10	0	10	0	10

MORPHINE (MOP 100)

Morphine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
50	10	10	0	10	0	10	0
75	10	9	1	9	1	9	1
125	10	1	9	1	9	1	9
150	10	0	10	0	10	0	10

METHAQUALONE (MQL 300)

Methaqualone conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
150	10	10	0	10	0	10	0
225	10	9	1	9	1	9	1
375	10	1	9	1	9	1	9
450	10	0	10	0	10	0	10

MORPHINE/OPIATE (OPI 2,000)

Morphine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
1,000	10	10	0	10	0	10	0
1,500	10	9	1	9	1	9	1
2,500	10	1	9	1	9	1	9
3,000	10	0	10	0	10	0	10

PHENCYCLIDINE (PCP)

Phencyclidine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
12.5	10	10	0	10	0	10	0
18.75	10	8	2	9	1	9	1
31.25	10	1	9	1	9	1	9
37.5	10	0	10	0	10	0	10

PROPOXYPHENE (PPX)

Propoxyphene conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
150	10	10	0	10	0	10	0
225	10	8	2	9	1	9	1
375	10	1	9	1	9	1	9
450	10	0	10	0	10	0	10

TRICYCLIC ANTIDEPRESSANTS (TCA)

Nortriptyline conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
500	10	10	0	10	0	10	0
750	10	9	1	8	2	8	2
1,250	10	1	9	1	9	1	9
1,500	10	0	10	0	10	0	10

TRAMADOL (TML 100)

Tramadol conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
50	10	10	0	10	0	10	0
75	10	9	1	9	1	8	2
125	10	1	9	1	9	2	8
150	10	0	10	0	10	0	10

TRAMADOL (TML 200)

Tramadol conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
100	10	10	0	10	0	10	0
150	10	9	1	9	1	8	2
250	10	1	9	1	9	2	8
300	10	0	10	0	10	0	10

TRAMADOL (TML 300)

Tramadol conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
150	10	10	0	10	0	10	0
225	10	9	1	9	1	8	2
375	10	1	9	1	9	2	8
450	10	0	10	0	10	0	10

KETAMINE (KET1, 000)

Ketamine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
500	10	10	0	10	0	10	0
750	10	9	1	8	2	9	1
1,250	10	1	9	1	9	2	8
1,500	10	0	10	0	10	0	10

KETAMINE (KET500)

Ketamine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
250	10	10	0	10	0	10	0
375	10	9	1	9	1	8	2
625	10	1	9	1	9	2	8
750	10	0	10	0	10	0	10

KETAMINE (KET300)

Ketamine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
150	10	10	0	10	0	10	0
225	10	9	1	9	1	9	1
375	10	1	9	1	9	1	9
450	10	0	10	0	10	0	10

KETAMINE (KET100)

Ketamine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
50	10	10	0	10	0	10	0
75	10	9	1	9	1	9	1
125	10	1	9	1	9	2	8
150	10	0	10	0	10	0	10

OXYCODONE (OXY100)

Oxycodone conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
50	10	10	0	10	0	10	0
75	10	9	1	9	1	9	1
125	10	1	9	1	9	1	9
150	10	0	10	0	10	0	10

COTININE (COT 200)

Cotinine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
100	10	10	0	10	0	10	0
150	10	9	1	9	1	9	1
250	10	1	9	1	9	2	8
300	10	0	10	0	10	0	10

COTININE (COT 100)

Cotinine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
50	10	10	0	10	0	10	0
75	10	9	1	9	1	9	1
125	10	1	9	1	9	1	9
150	10	0	10	0	10	0	10

2-ETHYLIDENE-1,5-DIMETHYL-3,3-DIPHENYLPYRROLIDINE (EDDP 300)

EDDP conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
150	10	10	0	10	0	10	0
225	10	9	1	9	1	9	1
375	10	1	9	2	8	1	9
450	10	0	10	0	10	0	10

2-ETHYLIDENE-1,5-DIMETHYL-3,3-DIPHENYLPYRROLIDINE (EDDP 100)

EDDP conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
50	10	10	0	10	0	10	0
75	10	9	1	9	1	9	1
125	10	1	9	1	9	1	9
150	10	0	10	0	10	0	10

FENTANYL (FYL20)

FYL conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
10	10	10	0	10	0	10	0
15	10	9	1	9	1	9	1
25	10	1	9	1	9	1	9
30	10	0	10	0	10	0	10

FENTANYL (FYL10)

FYL conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
5	10	10	0	10	0	10	0
7.5	10	9	1	9	1	9	1
12.5	10	1	9	1	9	1	9
15	10	0	10	0	10	0	10

K2 50

K2 conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
25	10	10	0	10	0	10	0
37.5	10	8	2	8	2	9	1
62.5	10	1	9	2	8	2	8
75	10	0	10	0	10	0	10

K2 30

K2 conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
15	10	10	0	10	0	10	0
22.5	10	8	2	9	1	9	1
37.5	10	1	9	1	9	1	9
45	10	0	10	0	10	0	10

K2 25

K2 conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
12.5	10	10	0	10	0	10	0
18.75	10	7	3	8	2	8	2
31.25	10	1	9	1	9	2	8
37.5	10	0	10	0	10	0	10

6-MAM

6-MAM conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
5	10	10	0	10	0	10	0
7.5	10	9	1	9	1	9	1
12.5	10	1	9	1	9	1	9
15	10	0	10	0	10	0	10

MDA 500

MDA conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
250	10	10	0	10	0	10	0
375	10	9	1	9	1	9	1
625	10	1	9	1	9	1	9
750	10	0	10	0	10	0	10

ETG500

Ethyl Glucuronide Concentration (ng/mL)	n per Site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
250	10	10	0	10	0	10	0
375	10	8	2	8	2	9	1
625	10	1	9	2	8	2	8
750	10	0	10	0	10	0	10

ETG1,000

Ethyl Glucuronide Concentration (ng/mL)	n per Site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
500	10	10	0	10	0	10	0
750	10	8	2	8	2	9	1
1250	10	1	9	2	8	2	8
1500	10	0	10	0	10	0	10

CLO 400

Clonazepam Concentration (ng/mL)	n per Site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
200	10	10	0	10	0	10	0
300	10	9	1	8	2	9	1
500	10	1	9	2	8	1	9
600	10	0	10	0	10	0	10

CLO 150

Clonazepam Concentration (ng/mL)	n per Site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
75	10	10	0	10	0	10	0
112	10	9	1	8	2	9	1
187	10	1	9	2	8	1	9
225	10	0	10	0	10	0	10

LSD 20

Clonazepam	n per	Site A		Site B		Site C	

Concentration (ng/mL)	Site	-	+	-	+	-	+
0	10	10	0	10	0	10	0
10	10	10	0	10	0	10	0
15	10	9	1	9	1	9	1
25	10	1	9	1	9	1	9
30	10	0	10	0	10	0	10

LSD 50

Clonazepam Concentration (ng/mL)	n per Site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
25	10	10	0	10	0	10	0
37.5	10	9	1	9	1	9	1
62.5	10	1	9	1	9	1	9
75	10	0	10	0	10	0	10

MPD

Methylphenidate (Ritalin) Concentration (ng/mL)	n per Site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
150	10	10	0	10	0	10	0
225	10	9	1	8	2	9	1
375	10	1	9	2	8	1	9
450	10	0	10	0	10	0	10

ZOL

Zolpidem Concentration (ng/mL)	n per Site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
25	10	9	1	10	0	10	0
75	10	0	10	1	9	0	10

MEPHEDRONE (MEP 100)

Mephedrone HCl Concentration. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
50	10	10	0	10	0	10	0
75	10	9	1	8	2	9	1
125	10	2	8	2	8	2	8
150	10	0	10	0	10	0	10

3, 4-METHYLENEDIOXYPYROVALERONE (MDPV1000)

3, 4-methylenedioxypyrovalerone Concentration (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
500	10	10	0	10	0	10	0
750	10	9	1	9	1	8	2
1250	10	1	9	1	9	1	9
1500	10	0	10	0	10	0	10

3, 4-METHYLENEDIOXYPYROVALERONE (MDPV500)

3, 4-methylenedioxypyrovalerone Concentration (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
250	10	10	0	10	0	10	0
375	10	9	1	9	1	8	2
625	10	2	8	1	9	1	9
750	10	0	10	0	10	0	10

DIAZEPAM (DIA 300)

Diazepam Concentration (ng/mL)	n per Site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
150	10	10	0	10	0	10	0
225	10	9	1	9	1	9	1
375	10	1	9	1	9	1	9
450	10	0	10	0	10	0	10

DIAZEPAM (DIA 200)

Diazepam Concentration (ng/mL)	n per Site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
100	10	10	0	10	0	10	0
150	10	9	1	9	1	9	1
250	10	1	9	1	9	1	9
300	10	0	10	0	10	0	10

ZOPICLONE (ZOP 50)

Zopiclone	n per	Site A		Site B		Site C	

Concentration (ng/mL)	Site	-	+	-	+	-	+
0	10	10	0	10	0	10	0
25	10	10	0	10	0	10	0
37.5	10	9	1	8	2	9	1
62.5	10	2	8	2	8	2	8
75	10	0	10	0	10	0	10

METHCATHINONE (MCAT 500)

Methcathinone Concentration (ng/mL)	n per Site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
250	10	10	0	10	0	10	0
375	10	9	1	8	2	9	1
625	10	2	8	2	8	2	8
750	10	0	10	0	10	0	10

7-ACL(300)

7- Aminoclonazepam Concentration (ng/mL)	n per Site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
150	10	10	0	10	0	10	0
225	10	8	2	9	1	9	1
375	10	2	8	2	8	3	7
450	10	0	10	0	10	0	10

7-ACL(200)

7- Aminoclonazepam Concentration (ng/mL)	n per Site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
100	10	10	0	10	0	10	0
150	10	8	2	9	1	8	2
250	10	2	8	2	8	2	8
300	10	0	10	0	10	0	10

7-ACL(100)

7- Aminoclonazepam Concentration (ng/mL)	n per Site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
50	10	10	0	10	0	10	0
75	10	7	3	7	3	9	1
125	10	2	8	1	9	2	8
150	10	0	10	0	10	0	10

CARFENTANYL(CFYL500)

Carfentanyl Concentration (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
250	10	10	0	10	0	10	0
375	10	7	3	9	1	8	2
625	10	2	8	1	9	2	8
750	10	0	10	0	10	0	10

CAFFEINE (CAF 1000)

Caffeine Concentration (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
500	10	10	0	10	0	10	0
750	10	9	1	8	2	9	1
1250	10	2	8	2	8	2	8
1500	10	0	10	0	10	0	10

CATHINE (CAT 150)

(+)-Norpseudoephedrine HCl Concentration(ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
75	10	10	0	10	0	10	0
112.5	10	9	1	8	2	9	1
187.5	10	2	8	2	8	2	8
225	10	0	10	0	10	0	10

TROPICAMIDE (TRO)

Tropicamide Concentration (ng/ml)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
175	10	10	0	10	0	10	0
262.5	10	8	2	8	2	8	2
437.5	10	2	8	2	8	2	8
525	10	0	10	0	10	0	10

ALPRAZOLAM（ALP）

Alprazolam Concentration (ng/ml)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0

50	10	10	0	10	0	10	0
75	10	10	0	10	0	10	0
125	10	9	1	8	2	9	1
150	10	2	8	2	8	2	8

AB-PINACA (ABP10)

AB-PINACA Concentration (ng/mL)	n per Site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
5	10	10	0	10	0	10	0
7.5	10	8	2	8	2	9	1
12.5	10	2	8	3	7	1	9
15	10	0	10	0	10	0	10

Analytical Sensitivity

A drug-free urine pool was spiked with drugs at the listed concentrations. The results are summarized below.

Drug Concentration Cut-off Range	ACE 5000		AMP 1,000		AMP500		AMP 300		BAR 300		BAR 200		BZO500		BZO300	
	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-50% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-25% Cut-off	26	4	26	4	25	5	27	3	27	3	26	4	27	3	27	3
Cut-off	14	16	15	15	15	15	15	15	16	14	15	15	15	15	15	15
+25% Cut-off	3	27	3	27	3	27	4	26	4	26	3	27	4	26	3	27
+50% Cut-off	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30
+300% Cut-off	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30

Drug Concentration Cut-off Range	BZO200		BZO100		BUP 10		BUP 5		COC300		COC 200		COC 150		COC100	
	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-50% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-25% Cut-off	27	3	27	3	26	4	26	4	26	4	26	4	27	3	27	3
Cut-off	16	14	14	16	14	16	14	16	13	17	14	16	16	14	16	14
+25% Cut-off	3	27	3	27	3	27	3	27	3	27	3	27	4	26	4	26
+50% Cut-off	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30
+300% Cut-off	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30

Drug Concentration Cut-off Range	THC150		THC50		THC25		MTD300		MTD200		MET 1,000		MET500		MET300	
	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-50% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-25% Cut-off	27	3	26	4	27	3	26	4	25	5	27	3	27	3	27	3
Cut-off	15	15	14	16	15	15	14	16	15	15	16	14	16	14	15	15
+25% Cut-off	4	26	3	27	4	26	3	27	4	26	3	27	4	26	3	27
+50% Cut-off	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30
+300% Cut-off	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30

Drug Concentration Cut-off Range	MDMA 1,000		MDMA 500		MOP 300		MOP 100		OPI		PCP		PPX		TCA	
	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-50% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-25% Cut-off	26	4	25	5	27	3	26	4	27	3	25	5	26	4	25	5
Cut-off	15	15	14	16	15	15	15	15	14	16	15	15	15	15	15	15
+25% Cut-off	5	25	4	26	5	25	3	27	4	26	3	27	3	27	4	26
+50% Cut-off	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30
+300% Cut-off	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30

Drug Concentration Cut-off Range	TML 100		TML 200		TML 300		KET 1,000		KET 500		KET 300		KET 100		MQL	
	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-50% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-25% Cut-off	27	3	27	3	27	3	27	3	27	3	26	4	27	3	26	4
Cut-off	15	15	15	15	15	15	15	15	15	16	14	15	15	15	15	15
+25% Cut-off	4	26	4	26	3	27	3	27	4	26	4	26	3	27	4	26
+50% Cut-off	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30
+300% Cut-off	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30

Drug Concentration Cut-off Range	OXY		COT 200		COT 100		EDDP 300		EDDP 100		FYL 20		FYL 10		K2 50	
	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-50% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-25% Cut-off	27	3	27	3	27	3	27	3	26	4	27	3	27	3	27	3
Cut-off	15	15	15	15	14	16	15	15	15	15	14	16	15	15	15	15
+25% Cut-off	4	26	4	26	4	26	4	26	3	27	4	26	3	27	3	27
+50% Cut-off	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30
+300% Cut-off	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30

Drug Concentration Cut-off Range	K2 30		6-MAM 10		MDA 500		ETG500		ETG1000		CLO 400		CLO 150		LSD20	
	-	+	-	+	-	+	-	+	-	+	-	+	-	+		+
0% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-50% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-25% Cut-off	27	3	27	3	26	4	26	4	26	4	26	4	26	4	27	3
Cut-off	16	14	15	15	15	15	15	15	15	15	14	16	14	16	14	16
+25% Cut-off	4	26	4	26	3	27	3	27	3	27	5	25	5	25	3	27
+50% Cut-off	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30
+300% Cut-off	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30

Drug Concentration Cut-off Range	LSD50		MPD		ZOL		MDMA 300		THC 200		MOP 200		MEP 100		MDPV 1000	
	-	+	-	+	-	+	-	-	+	+	-	+	-	+	-	+
0% Cut-off	30	0	30	0	30	0	30	30	0	0	30	0	30	0	30	0
-50% Cut-off	30	0	29	1	30	0	30	30	0	0	30	0	30	0	30	0
-25% Cut-off	27	3	*	*	26	4	25	27	3	5	26	4	24	6	26	4
Cut-off	14	16	15	15	14	16	15	17	13	15	15	15	17	13	14	16
+25% Cut-off	3	27	*	*	5	25	3	5	25	27	4	26	4	26	3	27
+50% Cut-off	0	30	1	29	0	30	0	0	30	30	0	30	0	30	0	30
+300% Cut-off	0	30	0	30	0	30	0	0	30	30	0	30	0	30	0	30

Drug Concentration Cut-off Range	DIA 300		DIA 200		THC300		THC30		K2 25		ZOP 50		MCAT 500		MDPV 500	
	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-50% Cut-off	30	0	29	1	30	0	30	0	30	0	30	0	30	0	30	0
-25% Cut-off	27	3	27	3	27	3	26	4	25	5	27	3	28	2	25	5
Cut-off	15	15	15	15	14	16	14	16	14	16	17	13	17	13	15	15
+25% Cut-off	3	27	3	27	4	26	4	26	3	27	4	26	3	27	3	27
+50% Cut-off	0	30	1	29	0	30	0	30	0	30	0	30	0	30	0	30
+300% Cut-off	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30

Drug Concentration Cut-off Range	7-ACL 300		7-ACL 200		7-ACL 100		CFYL 500		CAF 1000		CAT 150		TRO 350		ALP	
	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-50% Cut-off	30	0	30	0	29	1	30	0	30	0	30	0	30	0	30	0
-25% Cut-off	26	4	27	3	27	3	25	5	27	3	27	3	27	3	28	2
Cut-off	14	16	14	16	13	17	14	16	17	13	17	13	15	15	17	13
+25% Cut-off	5	25	3	27	4	26	6	24	5	25	4	26	3	27	3	27
+50% Cut-off	0	30	0	30	1	29	0	30	0	30	0	30	0	30	0	30
+300% Cut-off	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30

Drug Concentration Cut-off Range	ABP 10	
	-	+
0% Cut-off	30	0
-50% Cut-off	30	0
-25% Cut-off	25	5
Cut-off	15	15
+25% Cut-off	4	26
+50% Cut-off	0	30
+300% Cut-off	0	30

Analytical Specificity

The following table lists the concentrations of compounds (ng/mL) that are detected as positive in urine by the Multi-Drug Rapid Test Panel at 5 minutes.

Analytes	**Concentration (ng/mL)**	**Analytes**	**Concentration (ng/mL)**
ACETAMINOPHEN (ACE)			
Acetaminophen	5,000		
AMPHETAMINE (AMP 1,000)			
D,L-Amphetamine sulfate	300	Phentermine	1,000
L-Amphetamine	25,000	Maprotiline	50,000
(±) 3,4-Methylenedioxy amphetamine	500	Methoxyphenamine	6,000
		D-Amphetamine	1,000
AMPHETAMINE (AMP 500)			
D,L-Amphetamine sulfate	150	Phentermine	500
L-Amphetamine	12,500	Maprotiline	25,000
(±) 3,4-Methylenedioxy amphetamine	250	Methoxyphenamine	3,000
		D-Amphetamine	500
AMPHETAMINE (AMP 300)			
D,L-Amphetamine sulfate	75	Phentermine	300
L-Amphetamine	10,000	Maprotiline	15,000
(±) 3,4-Methylenedioxy amphetamine	150	Methoxyphenamine	2,000
		D-Amphetamine	300

BARBITURATES (BAR 300)			
Amobarbital	5,000	Alphenol	600
5,5-Diphenylhydantoin	8,000	Aprobarbital	500
Allobarbital	600	Butabarbital	200
Barbital	8,000	Butalbital	8,000
Talbutal	200	Butethal	500
Cyclopentobarbital	30,000	Phenobarbital	300
Pentobarbital	8,000	Secobarbital	300
BARBITURATES (BAR 200)			
Amobarbital	3,000	Alphenol	400
5,5-Diphenylhydantoin	5,000	Aprobarbital	300
Allobarbital	400	Butabarbital	150
Barbital	5,000	Butalbital	5,000
Talbutal	150	Butethal	300
Cyclopentobarbital	20,000	Phenobarbital	200
Pentobarbital	5,000	Secobarbital	200
BENZODIAZEPINES (BZO 500)			
Alprazolam	200	Bromazepam	1,500
a-hydroxyalprazolam	2,500	Chlordiazepoxide	1,500
Clobazam	300	Nitrazepam	300
Clonazepam	800	Norchlordiazepoxide	200
Clorazepatedipotassium	800	Nordiazepam	1,500
Delorazepam	1,500	Oxazepam	500
Desalkylflurazepam	300	Temazepam	300
Flunitrazepam	300	Diazepam	500
(±) Lorazepam	5,000	Estazolam	10,000
RS-Lorazepamglucuronide	300	Triazolam	5,000
Midazolam	10,000		
BENZODIAZEPINES (BZO 300)			
Alprazolam	100	Bromazepam	900
a-hydroxyalprazolam	1,500	Chlordiazepoxide	900
Clobazam	200	Nitrazepam	200
Clonazepam	500	Norchlordiazepoxide	100
Clorazepatedipotassium	500	Nordiazepam	900
Delorazepam	900	Oxazepam	300
Desalkylflurazepam	200	Temazepam	100
Flunitrazepam	200	Diazepam	300
(±) Lorazepam	3,000	Estazolam	6,000
RS-Lorazepamglucuronide	200	Triazolam	3,000
Midazolam	6,000		
BENZODIAZEPINES (BZO 200)			
Alprazolam	70	Bromazepam	600
a-hydroxyalprazolam	1,000	Chlordiazepoxide	600
Clobazam	120	Nitrazepam	120
Clonazepam	300	Norchlordiazepoxide	70
Clorazepatedipotassium	300	Nordiazepam	600
Delorazepam	600	Oxazepam	200
Desalkylflurazepam	120	Temazepam	70
Flunitrazepam	120	Diazepam	200
(±) Lorazepam	2,000	Estazolam	4,000
RS-Lorazepamglucuronide	120	Triazolam	2,000
Midazolam	4,000		
BENZODIAZEPINES (BZO 100)			
Alprazolam	40	Bromazepam	300
a-hydroxyalprazolam	500	Chlordiazepoxide	300
Clobazam	60	Nitrazepam	60
Clonazepam	150	Norchlordiazepoxide	40
Clorazepatedipotassium	150	Nordiazepam	300
Delorazepam	300	Oxazepam	100
Desalkylflurazepam	60	Temazepam	40
Flunitrazepam	60	Diazepam	100
(±) Lorazepam	1,000	Estazolam	2,000
RS-Lorazepamglucuronide	60	Triazolam	1,000
Midazolam	2,000		
BUPRENORPHINE (BUP 10)			
Buprenorphine	10	Norbuprenorphine	50
Buprenorphine 3-D-Glucuronide	50	Norbuprenorphine 3-D-Glucuronide	100
BUPRENORPHINE (BUP 5)			
Buprenorphine	5	Norbuprenorphine	25
Buprenorphine 3-D-Glucuronide	25	Norbuprenorphine 3-D-Glucuronide	50
COCAINE (COC 300)			
Benzoylecgonine	300	Cocaethylene	20,000
Cocaine HCl	200	Ecgonine	30,000
COCAINE (COC 200)			
Benzoylecgonine	200	Cocaethylene	13,500
Cocaine HCl	135	Ecgonine	20,000
COCAINE (COC 150)			
Benzoylecgonine	150	Cocaethylene	1,0000
Cocaine HCl	120	Ecgonine	15,000
COCAINE (COC 100)			
Benzoylecgonine	100	Cocaethylene	7,000
Cocaine HCl	80	Ecgonine	10,000
MARIJUANA (THC300)			
Cannabinol	200,000	Δ8-THC	100,000
11-nor-Δ8-THC-9 COOH	200	Δ9-THC	100,000
11-nor-Δ9-THC-9 COOH	300		

MARIJUANA (THC200)			
Cannabinol	140,000	∆8-THC	68,000
11-nor-∆8-THC-9 COOH	120	∆9-THC	68,000
11-nor-∆9-THC-9 COOH	200		
MARIJUANA (THC150)			
Cannabinol	100,000	∆8-THC	50,000
11-nor-∆8-THC-9 COOH	100	∆9-THC	50,000
11-nor-∆9-THC-9 COOH	150		
MARIJUANA (THC50)			
Cannabinol	35,000	∆8-THC	17,000
11-nor-∆8-THC-9 COOH	30	∆9-THC	17,000
11-nor-∆9-THC-9 COOH	50		
MARIJUANA (THC30)			
Cannabinol	20,000	∆8-THC	10,000
11-nor-∆8-THC-9 COOH	20	∆9-THC	10,000
11-nor-∆9-THC-9 COOH	30		
MARIJUANA (THC25)			
Cannabinol	17,500	∆8-THC	8,500
11-nor-∆8-THC-9 COOH	15	∆9-THC	8,500
11-nor-∆9-THC-9 COOH	25		
METHADONE (MTD300)			
Methadone	300	Doxylamine	100,000
METHADONE (MTD200)			
Methadone	200	Doxylamine	65,000
METHAMPHETAMINE (MET1, 000)			
p-Hydroxymethamphetamine	25,000	(±)-3,4-Methylenedioxy-methamphetamine	12,500
D-Methamphetamine	1,000		
L-Methamphetamine	20,000	Mephentermine	50,000
METHAMPHETAMINE (MET500)			
p-Hydroxymethamphetamine	12,500	(±)-3,4-Methylenedioxy-methamphetamine	6,250
D-Methamphetamine	500		
L-Methamphetamine	10,000	Mephentermine	25,000
METHAMPHETAMINE (MET300)			
p-Hydroxymethamphetamine	7,500	(±)-3,4-Methylenedioxy-methamphetamine	3,750
D-Methamphetamine	300		
L-Methamphetamine	6,000	Mephentermine	15,000
METHYLENEDIOXYMETHAMPHETAMINE (MDMA1, 000) Ecstasy			
(±) 3,4-Methylenedioxy methamphetamine HCl	1,000	3,4-Methylenedioxyethyl-amphetamine	600
(±)3,4-Methylenedioxy amphetamine HCl	6,000		
METHYLENEDIOXYMETHAMPHETAMINE (MDMA500) Ecstasy			
(±) 3,4-Methylenedioxy methamphetamine HCl	500	3,4-Methylenedioxyethyl-amphetamine	300
(±) 3,4-Methylenedioxy amphetamine HCl	3,000		
METHYLENEDIOXYMETHAMPHETAMINE (MDMA300) Ecstasy			
(±) 3,4-Methylenedioxy methamphetamine HCl	300	3,4-Methylenedioxyethyl-amphetamine	180
(±) 3,4-Methylenedioxy amphetamine HCl	1,800		
MORPHINE (MOP 300)			
Codeine	200	Norcodeine	6,000
Levorphanol	1,500	Normorphone	50,000
Morphine-3-β-D-Glucuronide	800	Oxycodone	30,000
Ethylmorphine	6,000	Oxymorphone	50,000
Hydrocodone	50,000	Procaine	15,000
Hydromorphone	3,000	Thebaine	6,000
6-Monoacethylmorphine	300	Morphine	300
MORPHINE (MOP 200)			
Codeine	160	Norcodeine	4,000
Levorphanol	1,000	Normorphone	40,000
Morphine-3-β-D-Glucuronide	600	Oxycodone	20,000
Ethylmorphine	4,000	Oxymorphone	40,000
Hydrocodone	40,000	Procaine	10,000
Hydromorphone	2,000	Thebaine	4,000
6-Monoacethylmorphine	200	Morphine	200
MORPHINE (MOP 100)			
Codeine	80	Norcodeine	2,000
Levorphanol	500	Normorphone	20,000
Morphine-3-β-D-Glucuronide	300	Oxycodone	10,000
Ethylmorphine	2,000	Oxymorphone	20,000
Hydrocodone	20,000	Procaine	5,000
Hydromorphone	1,000	Thebaine	2,000
6-Monoacethylmorphine	200	Morphine	100
Methaqualone (MQL 300)			
Methaqualone	300		
MORPHINE/OPIATE (OPI 2,000)			
Codeine	2,000	Morphine	2,000
Ethylmorphine	3,000	Norcodeine	25,000
Hydrocodone	50,000	Normorphone	50,000
Hydromorphone	15,000	Oxycodone	25,000
Levorphanol	25,000	Oxymorphone	25,000
6-Monoacetylmorphine	3,000	Procaine	50,000
Morphine 3-β-D-glucuronide	2,000	Thebaine	25,000
PHENCYCLIDINE (PCP)			
Phencyclidine	25	4-Hydroxyphencyclidine	12,500
PROPOXYPHENE (PPX)			
D-Propoxyphene	300	**D-Norpropoxyphene**	300
TRICYCLIC ANTIDEPRESSANTS (TCA)			
Nortriptyline	1,000	Imipramine	400
Nordoxepine	500	Clomipramine	50,000
Trimipramine	3,000	Doxepine	2,000
Amitriptyline	1,500	Maprotiline	2,000
Promazine	3,000	Promethazine	50,000
Desipramine	200	Perphenazine	50,000
Cyclobenzaprine	2,000	Dithiaden	10,000
TRAMADOL (TML 100)			
n-Desmethyl-cis-tramadol	200	o-Desmethyl-cis-tramadol	10,000
Cis-tramadol	100	Phencyclidine	100,000
Procyclidine	100,000	d,l-O-Desmethyl venlafaxine	50,000
TRAMADOL (TML 200)			
n-Desmethyl-cis-tramadol	400	o-Desmethyl-cis-tramadol	20,000
Cis-tramadol	200	Phencyclidine	200,000
Procyclidine	200,000	d,l-O-Desmethyl venlafaxine	100,000
TRAMADOL (TML 300)			
n-Desmethyl-cis-tramadol	600	o-Desmethyl-cis-tramadol	30,000
Cis-tramadol	300	Phencyclidine	300,000
Procyclidine	300,000	d,l-O-Desmethyl venlafaxine	150,000
KETAMINE (KET1, 000)			
Ketamine	1,000	Benzphetamine	25,000
Dextromethorphan	2,000	(+) Chlorpheniramine	25,000
Methoxyphenamine	25,000	Clonidine	100,000
d-Norpropoxyphene	25,000	EDDP	50,000
Promazine	25,000	4-Hydroxyphencyclidine	50,000
Promethazine	25,000	Levorphanol	50,000
Pentazocine	25,000	MDE	50,000
Phencyclidine	25,000	Meperidine	25,000
Tetrahydrozoline	500	d-Methamphetamine	50,000
Mephentermine	25,000	l-Methamphetamine	50,000
(1R, 2S) - (-)-Ephedrine	100,000	3,4-Methylendioxymethamphetamine (MDMA)	100,000
Disopyramide	25,000	Thioridazine	50,000
KETAMINE (KET500)			
Ketamine	500	Benzphetamine	12,500
Dextromethorphan	1,000	(+) Chlorpheniramine	12,500
Methoxyphenamine	12,500	Clonidine	50,000
d-Norpropoxyphene	12,500	EDDP	25,000
Promazine	12,500	4-Hydroxyphencyclidine	25,000
Promethazine	12,500	Levorphanol	25,000
Pentazocine	12,500	MDE	25,000
Phencyclidine	12,500	Meperidine	12,500
Tetrahydrozoline	250	d-Methamphetamine	25,000
Mephentermine	12,500	l-Methamphetamine	25,000
(1R, 2S) - (-)-Ephedrine	50,000	3,4-Methylendioxymethamphetamine (MDMA)	50,000
Disopyramide	12,500	Thioridazine	25,000
KETAMINE (KET300)			
Ketamine	300	Benzphetamine	6,250
Dextromethorphan	600	(+) Chlorpheniramine	6,250
Methoxyphenamine	6,250	Clonidine	30,000
d-Norpropoxyphene	6,250	EDDP	15,000
Promazine	6,250	4-Hydroxyphencyclidine	15,000
Promethazine	6,250	Levorphanol	15,000
Pentazocine	6,250	MDE	15,000
Phencyclidine	6,250	Meperidine	6,250
Tetrahydrozoline	150	d-Methamphetamine	15,000
Mephentermine	6,250	l-Methamphetamine	15,000
(1R, 2S) - (-)-Ephedrine	30,000	3,4-Methylendioxymethamphetamine (MDMA)	30,000
Disopyramide	6,250	Thioridazine	15,000
KETAMINE (KET100)			
Ketamine	100	Benzphetamine	2,000
Dextromethorphan	200	(+) Chlorpheniramine	2,000
Methoxyphenamine	2,000	Clonidine	10,000
d-Norpropoxyphene	2,000	EDDP	5,000
Promazine	2,000	4-Hydroxyphencyclidine	5,000
Promethazine	2,000	Levorphanol	5,000
Pentazocine	2,000	MDE	5,000
Phencyclidine	2,000	Meperidine	2,000
Tetrahydrozoline	50	d-Methamphetamine	5,000
Mephentermine	2,000	l-Methamphetamine	5,000
(1R, 2S) - (-)-Ephedrine	10,000	Thioridazine	5,000
Disopyramide	2,000	3,4-Methylendioxymethamphetamine (MDMA)	10,000
Oxycodone (OXY100)			
Oxycodone	100	Hydromorphone	50,000
Oxymorphone	300	Naloxone	25,000
Levorphanol	50,000	Naltrexone	25,000
Hydrocodone	25,000		
Cotinine (COT 200)			
(-)-Cotinine	200	(-)-Nicotine	5,000
Cotinine (COT 100)			
(-)-Cotinine	100	(-)-Nicotine	2,500
2-Ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP300)			
2-Ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP)			300
2-Ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP100)			
2-Ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP)			100
Fentanyl (FYL20)			
Alfentanyl	600,000	Buspirone	15,000
Fenfluramine	50,000	Fentanyl	100
Norfentanyl	20	Sufentanyl	50,000
Fentanyl (FYL10)			
Alfentanyl	300,000	Buspirone	8,000
Fenfluramine	25,000	Fentanyl	50
Norfentanyl	10	Sufentanyl	25,000
Synthetic Marijuana (K2-50)			
JWH-018 5-Pentanoic acid	50	JWH-073 4-butanoic acid	50
JWH-018 4-Hydroxypentyl	400	JWH-018 5-Hydroxypentyl	500
JWH-073 4-Hydroxybuty	500		
Synthetic Marijuana (K2-30)			
JWH-018 5-Pentanoic acid	30	JWH-073 4-butanoic acid	30
JWH-018 4-Hydroxypentyl	250	JWH-018 5-Hydroxypentyl	300
JWH-073 4-Hydroxybuty	300		
Synthetic Marijuana (K2-25)			
JWH-018 5-Pentanoic acid	25	JWH-073 4-butanoic acid	25
JWH-018 4-Hydroxypentyl	200	JWH-018 5-Hydroxypentyl	250
JWH-073 4-Hydroxybuty	250		
6-mono-aceto-morphine (6-MAM)			
6-Monoacethylmorphine	10	Morphine	100,000
(±) 3, 4-Methylenedioxyamphetamine (MDA 500)			
(±) 3,4-Methylenedioxy amphetamine	500	Methoxyphenamine	5,000
		D-Amphetamine	2,000
D,L-Amphetamine sulfate	400	Phentermine	2,000
L-Amphetamine	30,000	Maprotiline	100,000
Ethyl- β-D-Glucuronide(ETG500)			
Ethyl- β -D-Glucuronide	500	Propyl β-D-glucuronide	50,000
Morphine 3β-glucuronide	100,000	Morphine 6β-glucuronide	100,000
Glucuronic Acid	100,000	Ethanol	>100,000
Methanol	>100,000		
Ethyl- β-D-Glucuronide(ETG1,000)			
Ethyl- β -D-Glucuronide	1,000	Propyl β-D-glucuronide	100,000
Morphine 3β-glucuronide	>100,000	Morphine 6β-glucuronide	>100,000
Glucuronic Acid	>100,000	Ethanol	>100,000
Methanol	>100,000		
CLONAZEPAM(CLO 400)			
Clonazepam	400	Flunitrazepam	300
Alprazolam	200	(±) Lorazepam	1,250
a-hydroxyalprazolam	2,000	RS-Lorazepamglucuronide	250
Bromazepam	1,000	Midazolam	5,000
Chlordiazepoxide	1,000	Nitrazepam	200
Clobazam	250	Norchlordiazepoxide	200
Clorazepatedipotassium	600	Nordiazepam	1,000
Delorazepam	1,000	Oxazepam	350
Desalkylflurazepam	250	Temazepam	150
Diazepam	300	Triazolam	5,000
Estazolam	1,250		
CLONAZEPAM(CLO 150)			
Clonazepam	150	Flunitrazepam	120
Alprazolam	75	(±) Lorazepam	500
a-hydroxyalprazolam	750	RS-Lorazepamglucuronide	100
Bromazepam	400	Midazolam	2,000
Chlordiazepoxide	400	Nitrazepam	75
Clobazam	100	Norchlordiazepoxide	75
Clorazepatedipotassium	250	Nordiazepam	400
Delorazepam	400	Oxazepam	130
Desalkylflurazepam	100	Temazepam	60
Diazepam	120	Triazolam	2,000
Estazolam	500		
LYSERGIC ACID DIETHYLAMIDE (LSD 20)			
Lysergic Acid Diethylamide	20		
LYSERGIC ACID DIETHYLAMIDE (LSD 50)			
Lysergic Acid Diethylamide	50		
METHYLPHENIDATE (RITALIN)			
Methylphenidate (Ritalin)	300	Ritalinic Acid	1,000
ZOLPIDEM			
Zolpidem	50		
Mephedrone(MEP100)			
Mephedrone HCl	100	R(+)-Methcathinone HCl	1500
S(-)-Methcathinone HCl	500	3-Fluoromethcathinone HCl	1500
4-Fluoromethcathinone HCl	300	Methoxyphenamine	100,000
3, 4-methylenedioxypyrovalerone (MDPV1000)			
3, 4-methylenedioxypyrovalerone	1000		
3, 4-methylenedioxypyrovalerone (MDPV500)			
3, 4-methylenedioxypyrovalerone	500		
Diazepam (DIA 300)			
Diazepam	300	Midazolam	6,000
Clobazam	200	Nitrazepam	200
Clonazepam	500	Norchlordiazepoxide	100

Clorazepate dipotassium	500	Nordiazepam	900
Alprazolam	100	Flunitrazepam	200
a-hydroxyalprazolam	1,500	(±) Lorazepam	3,000
Bromazepam	900	RS-Lorazepam glucuronide	200
Chlordiazepoxide	900	Triazolam	3,000
Estazolam	6,000	Temazepam	100
Delorazepam	900	Oxazepam	300
Desalkylflurazepam	200		
Diazepam (DIA 200)			
Diazepam	200	Midazolam	4000
Clobazam	120	Nitrazepam	120
Clonazepam	300	Norchlordiazepoxide	70
Clorazepate dipotassium	300	Nordiazepam	600
Alprazolam	70	Flunitrazepam	120
a-hydroxyalprazolam	1000	(±) Lorazepam	2000
Bromazepam	600	RS-Lorazepam glucuronide	120
Chlordiazepoxide	600	Triazolam	2000
Estazolam	4000	Temazepam	70
Delorazepam	600	Oxazepam	200
Desalkylflurazepam	120		
Zopiclone (ZOP 50)			
Zopiclone-x-oxide	50	Zopiclone	50
Methcathinone (MCAT 500)			
S(-)-Methcathinone HCl	500	R(+)-Methcathinone HCl	1500
Methoxyphenamine	100000	3-Fluoromethcathinone HCl	1500
7-AMINOCLONAZEPAM(7-ACL300)			
a-hydroxyalprazolam	6,000	Flunitrazepam	3,000
Bromazepam	6,000	RS-Lorazepam glucuronide	2,700
Chlordiazepoxide	6,000	Norchlordiazepoxide	4,500
Clobazam	9,000	Nordiazepam	15,000
Clonazepam	2,400	Temazepam	9,000
Delorazepam	6,000	7-Aminoclonazepam	300
Desalkylflurazepam	6,000		
7-AMINOCLONAZEPAM(7-ACL200)			
a-hydroxyalprazolam	4,000	Flunitrazepam	2,000
Bromazepam	4,000	RS-Lorazepam glucuronide	1,800
Chlordiazepoxide	4,000	Norchlordiazepoxide	3,000
Clobazam	6,000	Nordiazepam	10,000
Clonazepam	1,600	Temazepam	6,000
Delorazepam	4,000	7-Aminoclonazepam	200
Desalkylflurazepam	4,000		
7-AMINOCLONAZEPAM(7-ACL100)			
a-hydroxyalprazolam	2,000	Flunitrazepam	1,000
Bromazepam	2,000	RS-Lorazepam glucuronide	900
Chlordiazepoxide	2,000	Norchlordiazepoxide	1,500
Clobazam	3,000	Nordiazepam	5,000
Clonazepam	800	Temazepam	3,000
Delorazepam	2,000	7-Aminoclonazepam	100
Desalkylflurazepam	2,000		
CARFENTANYL(CFYL500)			
Carfentanyl	500	Fentanyl	100
Caffeine (CAF 1000)			
Caffeine	1000		
Cathine (CAT 150)			
(+)-Norpseudoephedrine HCl (Cathine)	150	(+)3,4-Methylenedioxyamphetamine (MDA)	100
d/l-Amphetamine	100	p-Hydroxyamphetamine	100
Tryptamine	12,500	Methoxyphenamine	12,500
Tropicamide (TRO 350)			
Tropicamide	350		
Alprazolam(ALP 100)			
Benzodiazepines	300	Flunitrazepam	200
a-hydroxyalprazolam	1,500	(±) Lorazepam	3,000
Bromazepam	900	RS-Lorazepamglucuronide	200
Chlordiazepoxide	900	Midazolam	6,000
Clobazam	200	Nitrazepam	200
Clonazepam	500	Norchlordiazepoxide	100
Clorazepatedipotassium	500	Nordiazepam	900
Delorazepam	900	Oxazepam	300
Desalkylflurazepam	200	Temazepam	100
Diazepam	300	Triazolam	3,000
Estazolam	6000		
AB-PINACA (ABP 10)			
AB-PINACA	10	UR-144 4-hydroxypentyl	10,000
AB-PINACA 5-Pentanoic	10	APINACA 5-hydroxypentyl	10,000
AB-PINACA 5-hydroxypentyl	10	ADB-PINACA N-(5-hydroxypentyl)	30
AB-FUBINACA	10	ADB-PINACA Pentanoic Acid	10
AB-PINACA 4-hydroxypentyl	10,000	5-fluoro AB-PINACA N-(4-hydroxypentyl)	30
UR-144 5-Pentanoic	5,000	5-fluoro AB-PINACA	25
UR-144 5-hydroxypentyl	10,000		

Effect of Urinary Specific Gravity

Fifteen (15) urine samples of normal, high, and low specific gravity ranges (1.005-1.045) were spiked with drugs at 50% below and 50% above cut-off levels respectively. The Multi-Drug Rapid Test Panel was tested in duplicate using fifteen drug-free urine and spiked urine samples. The results demonstrate that varying ranges of urinary specific gravity do not affect the test results.

Effect of Urinary pH

The pH of an aliquoted negative urine pool was adjusted to a pH range of 5 to 9 in 1 pH unit increments and spiked with drugs at 50% below and 50% above cut-off levels. The spiked, pH-adjusted urine was tested with the Multi-Drug Rapid Test Panel. The results demonstrate that varying ranges of pH do not interfere with the performance of the test.

Cross-Reactivity

A study was conducted to determine the cross-reactivity of the test with compounds in either drug-free urine or drug positive urine containing, Amphetamine, Barbiturates, Benzodiazepines, Buprenorphine, Cocaine, Marijuana, Methadone, Methamphetamine, Methylenedioxymethamphetamine, Morphine, Tramadol ,Ketamine ,Phencyclidine, Propoxyphene or Tricyclic Antidepressants, Oxycodone, Cotinine, EDDP, Fentanyl, Synthetic Marijuana,6-mono-aceto-morphine, 3, 4-Methylenedioxyamphetamine, Ethyl- β-D-Glucuronide, Clonazepam, Lysergic Acid Diethylamide, Methylphenidate, Zolpidem, 7-Aminoclonazepam,Carfentanyl Caffeine, Cathine, Tropicamide and AB-Pinaca. The following compounds show no cross-reactivity when tested with the Multi-Drug Rapid Test Panel at a concentration of 100 µg/mL.

Non Cross-Reacting Compounds

Acetophenetidin	Cortisone	Zomepirac	d-Pseudoephedrine
N-Acetylprocainamide	Creatinine	Ketoprofen	Quinidine
Acetylsalicylic acid	Deoxycorticosterone	Labetalol	Quinine
Aminopyrine	Dextromethorphan	Loperamide	Salicylic acid
Amoxicillin	Diclofenac	Meprobamate	Serotonin
Ampicillin	Diflunisal	Isoxsuprine	Sulfamethazine
l-Ascorbic acid	Digoxin	d,l-Propanolol	Sulindac
Apomorphine	Diphenhydramine	Nalidixic acid	Tetracycline
Aspartame	Ethyl-p-aminobenzoate	Naproxen	Tetrahydrocortisone,
Atropine	β-Estradiol	Niacinamide	3-acetate
Benzilic acid	Estrone-3-sulfate	Nifedipine	Tetrahydrocortisone
Benzoic acid	Erythromycin	Norethindrone	Tetrahydrozoline
Bilirubin	Fenoprofen	Noscapine	Thiamine
d,l-Brompheniramine	Furosemide	d,l-Octopamine	Thioridazine
Caffeine	Gentisic acid	Oxalic acid	d,l-Tyrosine
Cannabidiol	Hemoglobin	Oxolinic acid	Tolbutamide
Chloral hydrate	Hydralazine	Oxymetazoline	Triamterene
Chloramphenicol	Hydrochlorothiazide	Papaverine	Trifluoperazine
Chlorothiazide	Hydrocortisone	Penicillin-G	Trimethoprim
d,l-Chlorpheniramine	o-Hydroxyhippuric acid	Perphenazine	d,l-Tryptophan
Chlorpromazine	3-Hydroxytyramine	Phenelzine	Uric acid
Cholesterol	d,l-Isoproterenol	Prednisone	Verapamil
Clonidine			

【ALCOHOL PERFORMANCE CHARACTERISTICS】

The detection limit on the **Urine Alcohol Rapid Test** is from 0.02% to 0.30% for approximate relative blood alcohol level. The cutoff level of the **Urine Alcohol Rapid Test** can vary based on local regulations and laws. Test results can be compared to reference levels with color chart on the foil package.

【ALCOHOL ASSAY SPECIFICITY】

The **Urine Alcohol Rapid Test** will react with methyl, ethyl and allyl alcohols.

【ALCOHOL INTERFERING SUBSTANCES】

The following substances may interfere with the **Urine Alcohol Rapid Test** when using samples other than urine. The named substances do not normally appear in sufficient quantity in urine to interfere with the test.

A. Agents which enhance color development
- Peroxidases
- Strong oxidizers

B. Agents which inhibit color development
- Reducing agents: Ascorbic acid, Tannic acid, Pyrogallol, Mercaptans and tosylates, Oxalic acid, Uric Acid
- Bilirubin
- L-dopa
- L-methyldopa
- Methampyrone

【BIBLIOGRAPHY】

1. Hawks RL, CN Chiang. *Urine Testing for Drugs of Abuse*. National Institute for Drug Abuse (NIDA), Research Monograph 73, 1986.
2. Tietz NW. Textbook of Clinical Chemistry. W.B. Saunders Company. 1986; 1735.
3. Stewart DJ, Inaba T, Lucassen M, Kalow W. *Clin. Pharmacol. Ther*. April 1979; 25 ed: 464, 264-8.
4. Ambre J. *J. Anal. Toxicol.*1985; 9:241.
5. Winger, Gail, A Handbook of Drug and Alcohol Abuse, Third Edition, Oxford Press, 1992, page 146.
6. Robert DeCresce. *Drug Testing in the workplace,* 1989 page 114.
7. Glass, IB. The International Handbook of Addiction Behavior. Routledge Publishing, New York, NY. 1991; 216
8. B. Cody, J.T., "Specimen Adulteration in drug urinalysis. Forensic Sci. Rev., 1990, 2:63.
9. C. Tsai, S.C. et.al., J. Anal. Toxicol. 1998; 22 (6): 474
10. Baselt RC. Disposition of Toxic Drugs and Chemicals in Man. 6th Ed. Biomedical Publ., Foster City, CA 2002.
11. Hardman JG, Limbird LE. Goodman and Gilman's: The Pharmacological Basis for Therapeutics. 10th Edition. McGraw Hill Medical Publishing, 2001; 208-209.
12. Cumming, E. (22 April 2010). "Mephedrone: Chemistry lessons". London: The Daily Telegraph. Retrieved 2010-09-14.
13. "Drugs crackdown hailed a success". BBC News. 8 March 2010. Retrieved2010-03-31.
14. Kihara, Rhiannon; Day, Edward (May 2014). "Transient psychotic episodes following recreational use of NRG-3". Progress in Neurology and Psychiatry 18 (3): 14–18. doi:10.1002/pnp.331. Retrieved 22 March2015.
15. Schifano, F.; Albanese, A.; Fergus, S.; Stair, J. L.; Deluca, P.; Corazza, O.; Davey, Z.; Corkery, J.; Siemann, H.; Scherbaum, N.; Farre', M.; Torrens, M.; Demetrovics, Z.; Ghodse, A. H.; Psychonaut Web, M.; Rednet Research, G. (2010). "Mephedrone (4-methylmethcathinone; 'meow meow'): chemical, pharmacological and clinical issues".Psychopharmacology 214 (3):593–602. doi:10.1007/s00213-010-2070-x.ISSN 0033-3158. PMID 21072502.
16. "Assessment of Zopiclone" *(PDF).World Health Organization. Essential Medicines and Health Products World Health Organization. p.9 (Section 5. Pharmacokinetics)*. Retrieved5 December 2015.
17. Kratzsch C, Tenberken O, Peters FT et al. Screening, library-assisted identification, and validated quantification of 23 benzodiazepines, flumazenil, zaleplone, zolpidem, and zopiclone in plasma by liquid chromatography/mass spectrometry with atmospheric pressure chemical ionization. J. Mass Spec. 39: 856-872, 2004.
18. Gustavsen I, Al-Sammurraie M, Mørland J, Bramness JG. Impairment related to blood drug concentrations of zopiclone and zolpidem compared with alcohol in apprehended drivers. Accid. Anal. Prev. 41: 462-466, 2009.
19. R. Baselt, Disposition of Toxic Drugs and Chemicals i Man, 8th edition, Biomedical Publications, Foster City, CA, 2008, pp. 1677-1679.
20. Calkins RF, Aktan GB, Hussain KL (1995). "Methcathinone: the next illicit stimulant epidemic?". Journal of Psychoactive Drugs. 27 (3): 277–85. doi:10.1080/02791072.1995.10472472. PMID 8594170.
21. Methcathinone, https://en.wikipedia.org/wiki/Methcathinone.
22. Bersani, F. S.; Corazza, O.; Simonato, P.; Mylokosta, A.; Levari, E.; Lovaste, R.; Schifano, F. (2013). "Drops of madness? Recreational misuse of tropicamide collyrium; early warning alerts from Russia and Italy".General Hospital Psychiatry 35 (5):571–3.Baselt RC. Disposition of Toxic Drugs and Chemicals in Man. 2nd Ed. Biomedical Publ., Davis, CA. 1982; 488
23. Malenka RC, Nestler EJ, Hyman SE (2009). "Chapter 15: Reinforcement and Addictive Disorders". In Sydor A, Brown RY. Molecular Neuropharmacology: A Foundation for Clinical Neuroscience (2nd ed.).NewYork:McGraw-Hill Medical. p. 375. ISBN 9780071481274.
24. American Psychiatric Association (2013). "Substance-Related and Addictive Disorders". American Psychiatric Publishing. pp. 1–2. Retrieved 10 July 2015.
25. Juliano LM, Griffiths RR (2004). "A critical review of caffeine withdrawal: empirical validation of symptoms and signs, incidence, severity, and associated features". Psychopharmacology (Berl.) 176 (1):1–29. doi:10.1007/s00213-004-2000-x. PMID 15448977. Archived from the original on 29 January 2012.
26. Arnaud MJ. Pharmacokinetics and metabolism of natural methylxanthines in animal and man. Handb Exp Pharmacol 2011; 200:33-91.
27. Jeukendrup AE, Randell R-Fat burners: nutrition supplements that increase fat metabolism. Obes Rev 2011; 193:1-24.
28. Cumming, E. (22 April 2010). "Mephedrone: Chemistry lessons". London: The Daily Telegraph. Retrieved 2010-09-14.
29. "Drugs crackdown hailed a success". BBC News. 8 March 2010. Retrieved2010-03-31.
30. Kihara, Rhiannon; Day, Edward (May 2014). "Transient psychotic episodes following recreational use of NRG-3". Progress in Neurology and Psychiatry 18 (3): 14–18. doi:10.1002/pnp.331. Retrieved 22 March2015.
31. Schifano, F.; Albanese, A.; Fergus, S.; Stair, J. L.; Deluca, P.; Corazza, O.; Davey, Z.; Corkery, J.; Siemann, H.; Scherbaum, N.; Farre', M.; Torrens, M.; Demetrovics, Z.; Ghodse, A. H.; Psychonaut Web, M.; Rednet Research, G. (2010). "Mephedrone (4-methylmethcathinone; 'meow meow'): chemical, pharmacological and clinical issues".Psychopharmacology 214 (3):593–602. doi:10.1007/s00213-010-2070-x.ISSN 0033-3158. PMID 21072502.
32. Work Group on Panic Disorder (January 2009). APA Practice Guideline for the Treatment of Patients With Panic Disorder (2nd ed.).
33. "FDA approved labeling for Xanax revision 08/23/2011" (PDF).Federal Drug Administration. 2011-08-23. p. 4. Retrieved 2011-09-14.
"Xanax XR (Alprazolam) Clinical Pharmacology – Prescription Drugs and Medications". RxList. First DataBank. July 2008.
34. "AB-PINACA". Cayman Chemical. Retrieved 25 June 2015.
35. Banister, Samuel D.; Moir, Michael; Stuart, Jordyn; Kevin, Richard C.; Wood, Katie E.; Longworth, Mitchell; Wilkinson, Shane M.; Beinat, Corinne; Buchanan, Alexandra S.; Glass, Michelle; Connor, Mark; McGregor, Iain S.; Kassiou, Michael (2015). "Pharmacology of Indole and Indazole Synthetic Cannabinoid Designer Drugs AB-FUBINACA, ADB-FUBINACA, AB-PINACA, ADB-PINACA, 5F-AB-PINACA, 5F-ADB-PINACA, ADBICA, and 5F-ADBICA". ACS Chemical Neuroscience. 6 (9): 1546–59.
36. Jenny L Wiley; Julie A Marusich; Timothy W Lefever; Kateland R Antonazzo; Michael T Wallgren; Ricardo A Cortes; Purvi R Patel; Megan Grabenauer; Katherine N Moore; Brian F Thomas (June 2015). "AB-CHMINACA, AB-PINACA, and FUBIMINA: Affinity and Potency of Novel Synthetic Cannabinoids in Producing Δ9-Tetrahydrocannabinol-Like Effects in Mice". Journal of Pharmacology and Experimental Therapeutics. 354 (3): 328–39. PMC 4538877 Freely accessible.

Index of Symbols

	Attention, see instructions for use		Tests per kit	EC REP	Authorized Representative
IVD	For in vitro diagnostic use only		Use by		Do not reuse
2°C 30°C	Store between 2-30°C	LOT	Lot Number	REF	Catalog #
	Do not use if package is damaged		Manufacturer		Consult Instructions For Use

Hangzhou AllTest Biotech Co., Ltd.
#550, Yinhai Street
Hangzhou Economic & Technological Development Area
Hangzhou - 310018, P. R. China
www.alltests.com.cn

EC REP
MedNet GmbH
Borkstrasse 10
48163 Muenster
Germany

Multi-Drug greito testo panelis su mėginio klastojimo testu (iš šlapimo)
Pakuotės aprašymas

Instrukcija, skirta bet kurios šių narkotinių medžiagų kombinacijos tyrimui: ACE/AMP/BAR/BZO/BUP/COC/THC/MTD/MET/MDMA/MOP/MQL/OPI/PCP/PPX/TCA/TML/KET/OXY/COT/EDDP/FYL/K2/6-MAM/MDA/ETG/CLO/LSD/MPD/ZOL/MEP/ALC/MDPV/DIA/ZOP/MCAT/7-ACL/CFYL/CAF/CAT/TRO/ALP/ABP
Įskaitant mėginio tinkamumo tyrimą (*angl.k.* S.V.T.) dėl:
Oksidantų/PCC, specifinio tankio, pH, nitrito, glutaraldehido, kreatinino ir baliklio

Greitas tyrimas, skirtas vienalaikiam kokybiniam įvairių narkotinių medžiagų ir jų metabolitų aptikimui žmogaus šlapime. Skirta sveikatos priežiūros specialistams, įskaitant šalia paciento tyrimus atliekančius profesionalus. Imunologinis tyrimas yra skirtas tik in vitro diagnostikai.

【PASKIRTIS】

Multi-Drug greito testo panelis yra greitas chromatografinis imunologinis tyrimas, skirtas kokybiniam įvairių narkotinių medžiagų ir jų metabolitų aptikimui šlapime, esant šioms slenkstinėms koncentracijoms:

Testas	Kalibratorius	Slenkstinė vertė (ng/mL)
Acetaminophen (ACE 5,000)	Acetaminophen	5,000
Amphetamine (AMP1,000)	d-Amphetamine	1,000
Amphetamine (AMP 500)	d-Amphetamine	500
Amphetamine (AMP 300)	d-Amphetamine	300
Barbiturates (BAR 300)	Secobarbital	300
Barbiturates (BAR 200)	Secobarbital	200
Benzodiazepines (BZO 500)	Oxazepam	500
Benzodiazepines (BZO 300)	Oxazepam	300
Benzodiazepines (BZO 200)	Oxazepam	200
Benzodiazepines (BZO 100)	Oxazepam	100
Buprenorphine (BUP 10)	Buprenorphine	10
Buprenorphine (BUP 5)	Buprenorphine	5
Cocaine (COC 300)	Benzoylecgonine	300
Cocaine (COC 200)	Benzoylecgonine	200
Cocaine (COC 150)	Benzoylecgonine	150
Cocaine (COC 100)	Benzoylecgonine	100
Marijuana (THC300)	11-nor-Δ9-THC-9 COOH	300
Marijuana (THC200)	11-nor-Δ9-THC-9 COOH	200
Marijuana (THC150)	11-nor-Δ9-THC-9 COOH	150
Marijuana (THC 50)	11-nor-Δ9-THC-9 COOH	50
Marijuana (THC 30)	11-nor-Δ9-THC-9 COOH	30
Marijuana (THC 25)	11-nor-Δ9-THC-9 COOH	25
Methadone (MTD 300)	Methadone	300
Methadone (MTD 200)	Methadone	200
Methamphetamine (MET 1,000)	d-Methamphetamine	1,000
Methamphetamine (MET 500)	d-Methamphetamine	500
Methamphetamine (MET 300)	d-Methamphetamine	300
Methylenedioxymethamphetamine (MDMA 300)	d,l-Methylenedioxymethamphetamine	300
Methylenedioxymethamphetamine (MDMA 500)	d,l-Methylenedioxymethamphetamine	500
Methylenedioxymethamphetamine (MDMA 1,000)	d,l-Methylenedioxymethamphetamine	1,000
Morphine (MOP 300)	Morphine	300
Morphine (MOP 200)	Morphine	200
Morphine (MOP 100)	Morphine	100
Methaqualone(MQL)	Methaqualone	300
Opiate (OPI 2,000)	Morphine	2,000
Phencyclidine (PCP)	Phencyclidine	25
Propoxyphene (PPX)	Propoxyphene	300
Tricyclic Antidepressants (TCA)	Nortriptyline	1,000
Tramadol (TML 100)	Cis-Tramadol	100
Tramadol (TML 200)	Cis-Tramadol	200
Tramadol (TML 300)	Cis-Tramadol	300
Ketamine (KET 1,000)	Ketamine	1,000
Ketamine (KET 500)	Ketamine	500
Ketamine (KET 300)	Ketamine	300
Ketamine (KET100)	Ketamine	100
Oxycodone (OXY)	Oxycodone	100
Cotinine(COT200)	Cotinine	200
Cotinine(COT100)	Cotinine	100
2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP300)	2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine	300
2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP100)	2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine	100
Fentanyl(FYL20)	Norfentanyl	20
Fentanyl(FYL10)	Norfentanyl	10
Synthetic Marijuana (K2-50)	JWH-018、JWH-073	50
Synthetic Marijuana (K2-30)	JWH-018、JWH-073	30
Synthetic Marijuana (K2-25)	JWH-018、JWH-073	25
6-mono-aceto-morphine (6-MAM10)	6-MAM	10
(±) 3,4-Methylenedioxy-Amphetamine(MDA500)	(±) 3,4-Methylenedioxy-Amphetamine	500
Ethyl- β-D-Glucuronide(ETG500)	Ethyl- β -D-Glucuronide	500
Ethyl- β-D-Glucuronide(ETG1,000)	Ethyl- β -D-Glucuronide	1,000
Clonazepam(CLO 400)	Clonazepam	400
Clonazepam(CLO 150)	Clonazepam	150
Lysergic Acid Diethylamide (LSD)	Lysergic Acid Diethylamide	20
Lysergic Acid Diethylamide (LSD)	Lysergic Acid Diethylamide	50
Methylphenidate (MPD)	Methylphenidate	300
Zolpidem(ZOL)	Zolpidem	50
Mephedrone	Mephedrone	100
3, 4-methylenedioxypyrovalerone (MDPV1000)	3, 4-methylenedioxypyrovalerone	1000
3, 4-methylenedioxypyrovalerone (MDPV 500)	3, 4-methylenedioxypyrovalerone	500
Diazepam(DIA 300)	Diazepam	300
Diazepam(DIA 200)	Diazepam	200
Zopiclone（ZOP 50）	Zopiclone	50
Methcathinone（MCAT 500）	S(-)-Methcathinone	500
7-Aminoclonazepam(7-ACL300)	7-Aminoclonazepam	300
7-Aminoclonazepam(7-ACL200)	7-Aminoclonazepam	200
7-Aminoclonazepam(7-ACL100)	7-Aminoclonazepam	100
Carfentanyl(CFYL500)	Carfentanyl	500
Caffeine(CAF)	Caffeine	1000
Cathine (CAT)	(+)-Norpseudoephedrine	150
Tropicamide(TRO)	Tropicamide	350
Alprazolam(ALP)	Alprazolam	100
AB-PINACA(ABP)	AB-PINACA	10
Testas	**Kalibratorius**	**Slenkstinė vertė**
Alcohol(ALC)	Alcohol	0.02%

Multi-Drug greito testo panelio konfigūracija gali būti su bet kuria aukščiau išvardintos narkotinės medžiagos analite, su arba be S.V.T. Šis testas suteikia tik preliminarų analitinio tyrimo rezultatą. Norint gauti patvirtintą analitinį rezultatą, reikia atlikti specifinį pakaitinį cheminį metodą. Rekomenduojamas patvirtinimo metodas yra dujų chromatografija/masės spektometrija (GC/MS). Kliniškai ir profesionaliai sprendimas turi būti priimtas vertinant bet kokius narkotikų piktnaudžiavimo testus, ypač vertinant preliminarų teigiamą rezultatą.

【SANTRAUKA】

Multi-Drug greito testo panelis yra greitas šlapimo skryningo tyrimas, kuris gali būti atliekamas nenaudojant instrumento. Tyrime yra naudojami monokloniniai antikūnai selektyviam padidėjusio specifinės narkotinės medžiagos kiekio aptikimui šlapime.

【KAS YRA KLASTOJIMAS】

Klastojimas – tai šlapimo mėginio suklastojimas, siekiant pakeisti tyrimo rezultatus. Pašalinės medžiagos gali sukelti klaidingai neigiamus tyrimo rezultatus interferuojant skryningo tyrimą ir/ar sunaikinant šlapime esančias narkotines medžiagas. Siekiant klaidingai neigiamo rezultato, gali būti atliekamas mėginio skiedimas.

Geriausias klastojimo nustatymo testas yra tam tikros šlapimo charakteristikos tikrinimas, pvz., pH, specifinio tankio ir kreatinino tyrimas bei oksidantų/PCC nitritų ar glutaraldehido šlapime tyrimas.

Oksidantai/PCC (Piridinio chlorochromatas) – nustatomas oksiduojančių agentų, tokių kaip baliklis ir vandenilio peroksidas, buvimas. Piridinio chlorochromatas (parduodamas prekiniu pavadinimu “Urine Luck”) yra plačiai naudojamas kaip klastojimo priemonė.[8] Normaliame žmogaus šlapime neturi būti oksidantų ar PCC.

Specifinis tankis – tiriamas mėginio skiedimas. Normalios ribos yra nuo 1.003 iki 1.030. Reikšmės už šio diapazono gali būti skiedimo ar klastojimo pasekmė.

Ph – tiriamas rūgščių ar šarmų buvimas šlapime. Normalus pH kiekis turi būti nuo 4.0 iki 9.0. Reikšmės už šio diapazono gali būti skiedimo ar klastojimo pasekmė.

Nitritai – tiriamas dažnai naudojamų komerciškai įsigyjamų klastojimo medžiagų, tokių kaip “Klear” ir “Whizzies” buvimas. Šios medžiagos oksiduoja kanabinoidinį metabolite THC-COOH.[9] Normaliame šlapime neturi būti nitrito pėdsakų. Teigiamas rezultatas reiškia mėginio klastojimą.

Glutaraldehidas – tiriamas aldehido buvimas. Medžiagose, tokiose kaip “Urin Aid” ir “Clear Choice” yra glutaraldehido, kuris gali sukelti klaidingai neigiamus rezultatus, suardant fermentą, naudojama kai kuriuose imunologiniuose tyrimuose.[9] Glutaraldehidas paprastai nėra aptinkamas šlapime, todėl jo aptikimas mėginyje yra mėginio klastojimo indikatorius.

Kreatininas yra šalutinis kreatino produktas; amino rūgštis, esanti raumenų audinyje ir aptinkama šlapime.[2] Asmuo gali gerti didelį kiekį vandens ar vartoti diuretikus, pvz., žolelių arbatas, taip “praplaunant” organizmą. Kreatinino ir specifinio tankio tyrimas – du būdai patikrinti skiedimą ar praplovimą – dažniausiai pasitaikančius mėginio klastojimo būdus. Mažas kreatinino ir specifinio tankio lygis gali indikuoti apie mėginio skiedimą. Kreatinino nebuvimas (<5 mg/dl) indikuoja, jog mėginys neatitinka žmogaus šlapimo mėginio.

Baliklis – tiriamas baliklio buvimas mėginyje. Baliklyje yra daug chemikalų, kurie panaikina spalvą, balina ar dezinfekuoja oksiduojant. Baliklis yra buitinė priemonė rūbų balinimui ar dėmių naikinimui bei yra naudojamas kaip dezinfekcinė priemonė. Normaliame žmogaus šlapime baliklio nėra.

【PRINCIPAS (DOA TYRIMAMS, IŠSKYRUS ALKOHOLĮ)】

Tyrimo metu, šlapimo mėginys migruoja aukštyn kapiliariniu būdu. Narkotinė medžiaga, esanti šlapime žemesne nei slenkstinė koncentracija, neprisotins specifinio antikūno susirišimo vietų. Tada antikūnas reaguos su narkotikų-baltymo konjugatu ir suformuos matomą spalvotą liniją specifinės narkotinės medžiagos tyrimo laukelyje. Jei narkotinės medžiagos koncentracija šlapime yra aukštesnė nei slenkstinė vertė, visos antikūnų susirišimo vietos bus prisotintos. Todėl, tyrimo laukelyje spalvota linija nesusiformuos.

Narkotinėms medžiagoms teigiamas šlapimo mėginys nesugeneruoja spalvotos linijos specifinio testo laukelyje dėl narkotinių medžiagų konkurencijos faktoriaus, o narkotinėms medžiagoms neigiamas šlapimo mėginys sugeneruos liniją testo laukelyje dėl narkotinių medžiagų konkurencijos faktoriaus nebuvimo.

Kaip procedūrinė kontrolė, kontrolės laukelyje visada atsiranda spalvota linija, reiškianti, jog buvo naudojamas tinkamas mėginio kiekis bei membrana veikia tinkamai.

【PRINCIPAS (ALKOHOLIUI)】

Greito alkoholio tyrimas yra plastikinė juostelė, kurios gale yra reakcijos laukelis. Įvykus kontaktui su alkoholiu, reakcijos laukelis pakeis spalvą, priklausomai nuo mėginyje esančios alkoholio koncentracijos. Tyrimas yra paremtas dideliu alkoholio oksidazės specifiškumu etilo alkoholiui, esant peroksidazei ir fermento substratui (TMB).

【REAGENTAI (DOA TYRIMAMS, IŠSKYRUS ALKOHOLĮ) 】

Kiekvienoje testo linijoje yra anti-narkotinių medžiagų pelės monokloninių antikūnų ir atitinkamų narkotinių medžiagų-baltymų konjugato. Kontrolės linijoje yra ožkos anti-triušio IgG polikloninių antikūnų ir triušio IgG.

【REAGENTAI (ALKOHOLIUI)】

Tetrametilbenzidinas
Alkoholio oksidazė
Peroksidazė

【S.V.T REAGENTAI】

Klastojimo nustatymo laukelis	Reaktyvumo indikatorius	Buferiai ir nereaktyvūs ingredientai
Kreatininas	0.04%	99.95%
Nitritas	0.07%	99.94%
Baliklis	0.39%	99.77%
Glutaraldehidas	0.02%	99.97%
pH	0.06%	99.94%
Specifinis tankis	0.25%	99.78%
Oksidantai / PCC	0.36%	99.70%

【ATSARGUMO PRIEMONĖS】

- Skirta sveikatos priežiūros specialistams, įskaitant šalia paciento tyrimus atliekančius profesionalus.
- Imunologinis tyrimas yra skirtas tik in vitro diagnostiniam naudojimui. Tyrimo panelis iki naudojimo turi būti laikomas sandarioje originalioje pakuotėje.
- Visi mėginiai turi būti laikomi potencialiai pavojingais ir su jais turi būti dirbama kaip su infekciškais agentais.
- Panaudotas tyrimo panelis turi būti išmetamas laikantis federalinių, valstybinių ir vietinių taisyklių.

【LAIKYMAS IR STABILUMAS】

Laikykite originalioje pakuotėje prie 2-30°C. Tyrimas yra stabilus iki galiojimo datos pabaigos, nurodytos ant pakuotės. Tyrimo panelis turi būti laikomas sandarioje pakuotėje iki jo naudojimo. NEUŽŠALDYKITE. Nenaudokite pasibaigus galiojimo datai.

【MĖGINIŲ SURINKIMAS IR PARUOŠIMAS】

Šlapimo tyrimas

Šlapimo mėginys turi būti surenkamas į švarų ir sausą konteinerį. Galima naudoti bet kuriuo paros metu surinktą šlapimo mėginį. Šlapimo mėginiai su matomomis nuosėdomis turi būti centrifuguojami, filtruojami arba juos reikia palaikyti, kol nuosėdos nusės ir mėginys taps skaidrus.

Mėginių laikymas

Prieš tyrimą mėginiai iki 48 valandų gali būti laikomi prie 2-8°C. Jei mėginius reikia sandėliuoti ilgiau, juos galima užšaldyti prie žemesnės nei -20°C. Prieš tyrimą užšaldyti mėginiai turi būti atitirpinami ir gerai išmaišom. Naudojant tyrimą su S.V.T. ar tiriant alkoholį, šlapimo mėginiai iki tyrimo negali būti laikomi ilgiau kaip 2 valandas kambario temperatūroje ir 4 valandas šaldytuve.

【MEDŽIAGOS】

Tiekiamos medžiagos

- Tyrimo paneliai
- Pakuotės aprašymas
- Klastojimo testo spalvinė lentelė (jei taikoma)

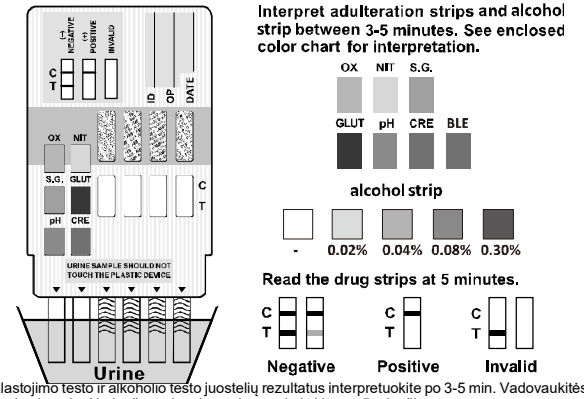
Reikalingos, tačiau netiekiamos medžiagos

- Laikmatis

【NAUDOJIMO INSTRUKCIJOS】

Prieš tyrimą, šlapimo mėginiams ir/ar kontrolėms leiskite pasiekti kambario temperatūrą (15-30ºC).

1. Prieš atidarant, pakuotė turi sušilti iki kambario temperatūros. Iš sandarios pakuotės išimkite tyrimo panelį ir sunaudokite per vieną valandą.
2. Nuimkite dangtelį.
3. Vadovaudamiesi rodykle, nukreipta į šlapimo mėginį, įmerkite tyrimo panelį į šlapimo mėginį ir palaikykite mažiausiai 10 – 15 sekundžių. **Įmerkite mėginio paėmimo galiukus bent iki banguotų linijų, tačiau ne aukščiau tyrimo panelio rodyklės.**
4. Uždėkite dangtelį ir padėkite tyrimo panelį ant nesugeriančio lygaus paviršiaus.
5. Įjunkite laikmatį ir palaukite, kol atsiras spalvota linija (-os).
6. Klastojimo testo ir alkoholio testo juosteles nuskaitykite po 3-5 minučių pagal spalvinę lentelę, pateikiamą atskirai ar ant folijos pakuotės. Dėl suklastotų mėginių vadovaukitės savo įstaigos politika dėl narkotikų. Gavus teigiamą rezultatą dėl mėginio klastojimo, nerekomenduojame interpretuoti tyrimo rezultatų ir pakartotinai atlikti tyrimą arba paimti kitą mėginį.
7. Narkotikų testo juostelė turi būti nuskaitoma po 5 minučių. Po 10 min. interpretuoti nebegalima.



Klastojimo testo ir alkoholio testo juostelių rezultatus interpretuokite po 3-5 min. Vadovaukitės pridedama spalvų lentele. Narkotikų tyrimo juosteles nuskaitykite po 5 minučių.

Urine – *liet.k.* šlapimas; Positive – *liet.k.* teigiamas; Negative – *liet.k.* neigiamas; Invalid - *liet.k.* klaidingas; Alcohol strip – *liet.k.* alkoholio juostelė

【REZULTATŲ INTERPRETAVIMAS】

(žr. aukščiau pateikiamą iliustraciją)

NEIGIAMAS:* kontrolės laukelyje (C) atsiranda spalvota linija (C) ir tyrimo laukelyje (T) atsiranda spalvota linija. Šis neigiamas rezultatas reiškia, specifinės tiriamosios narkotinės medžiagos

koncentracija šlapimo mėginyje yra žemiau numatytos slenkstinės reikšmės.
***PASTABA:** spalvotos linijos (-ų) tyrimo laukelyje (T) intensyvumas gali skirtis. Net jei atsiranda blanki linija, rezultatas turi būti interpretuojamas kaip neigiamas.
TEIGIAMAS: kontrolės laukelyje (C) atsiranda spalvota linija, o tyrimo laukelyje (T) linija NEATSIRANDA. Teigiamas rezultatas reiškia, jog specifinės tiriamosios narkotinės medžiagos koncentracija šlapimo mėginyje yra didesnė nei numatyta slenkstinė vertė.
NEGALIOJANTIS: kontrolės laukelyje (C) linija neatsiranda. Kontrolinės linijos nebuvimą gali įtakoti netinkamai atlikta procedūrinė technika. Dar kartą perskaitykite instrukcijas ir tyrimą pakartokite naudodami naują tyrimo kortelę. Jei tyrimo rezultatas vis tiek išlieka klaidingas, susisiekite su gamintoju.

【REZULTATŲ INTERPRETAVIMAS (S.V.T/ KLASTOJIMO) 】

(vadovaukitės spalvų lentele)

Pusiau kiekybiniai rezultatai yra gaunami vizualiai lyginant reagavusius juostelės laukelius su atspausdintomis spalvomis spalvų lentelėje.
Instrumentai nėra naudojami.

【REZULTATŲ INTERPRETAVIMAS (ALKOHOLIO JUOSTELĖ)】

Neigiamas: lyginant su fonu, spalva nepasikeitė. Neigiamas rezultatas reiškia, jog alkoholio kiekis šlapime yra mažesnis nei 0.02%.
Teigiamas: laukelio spalva aiškiai pasikeičia. Teigiamas rezultatas reiškia, jog alkoholio koncentracija šlapime yra 0.02% ar didesnė.
Negaliojantis: tyrimas turi būti laikomas negaliojančiu, jei pasikeitė tik reakcijos laukelio kampas, tai gali reikšti nepakankamą mėginio kiekį. Tirkite iš naujo. Jei, prieš įmerkiant į šlapimo mėginį laukelio spalva yra mėlyna, tyrimo priemonės nenaudokite.

【KOKYBĖS KONTROLĖ】

Tyrimo priemonėje yra vidinė procedūrinė kontrolė. Kontrolės laukelyje (C) atsirandanti linija yra vidinė procedūrinė kontrolė. Ji patvirtina, jog buvo naudotas pakankamas mėginio kiekis, membrana tinkamai pasidengė bei buvo atlikta teisinga procedūrinė technologija.
Kontrolės standartai nėra tiekiami su rinkiniu. Tačiau, laikantis geros laboratorijos praktikos, tyrimo veiksmingumo patvirtinimui rekomenduojama atlikti neigiamą ir teigiamą kontroles.

【APRIBOJIMAI】

1. greito testo panelis suteikia tik kokybinius preliminarius analitinius rezultatus. Norint gauti patvirtintą rezultatą, būtina atlikti antrinį analitinio metodo tyrimą. Rekomenduojamas patvirtinimo metodas gali būti dujų chromatografijos/masių spektroskopijos (GC/MC) metodas.[1,10]
2. Įmanoma, jog tyrimą gali interferuoti techninė ar procedūrinė klaida bei kiti neišvardinti faktoriai, ir sukelti klaidingus rezultatus.
3. Tam tikros medžiagos šlapime (baliklis ir/ar aliuminis) gali sukelti klaidingų rezultatų atsiradimą, nepriklausomai nuo naudojamo analitinio metodo. Jei įtariate apie šių medžiagų buvimą, tyrimą pakartokite su nauju šlapimo mėginiu.
4. Teigiamas rezultatas nenurodo kiekio ar intoksikacijos lygio, patekimo kelio ar koncentracijos šlapime.
5. Neigiamas rezultatas nebūtinai reiškia, jog šlapime nėra narkotinių medžiagų. Neigiamas rezultatas gali būti gaunamas, jei narkotinės medžiagos šlapime yra, tačiau jos koncentracija yra žemiau slenkstinės tyrimo vertės.
6. Šis tyrimas nenurodo skirtumo tarp piktnaudžiavimo narkotinėmis medžiagomis ir tam tikrų medikamentų vartojimo.
7. Teigiamas rezultatas gali būti gaunamas dėl tam tikrų maisto produktų ar maisto papildų vartojimo. Alkoholis aplinkoje, pvz., kvepaluose, dezodorantuose, langų valiklyje, gali turėti įtakos atliekant alkoholio testą. Todėl būtina imtis priemonių ir užkirsti kelią aplinkos agentų interferencijai tyrimo vietoje.
8. Tyrimas yra skirtas tik alkoholio buvimo ar nebuvimo šlapime nustatymui. Tyrimas neparodo skirtumo tarp alkoholio vartojimo ir alkoholio pasisavinimo vartojant vaistus.

【S.V.T/ KLASTOJIMO TESTO APRIBOJIMAI】

1. Klastojimo nustatymo testas yra pagalbinė priemonė nenormalių mėginių nustatyme. Šie tyrimai negali nustayti visų įmanomų klastojimo atvejų.
2. Oksidantai/PCC: normaliame žmogaus šlapime nėra oksidantų ar PCC. Didelis antioksidantų, tokių kaip askorbo rūgštis, kiekis šlapime gali sukelti klaidingai neigiamus rezultatus oksidantų/PCC laukelio rezultatus.
3. Specifinis tankis: didelis baltymų lygis šlapime gali sukelti neįprastai aukštos specifinio tankio vertės nustatymą.
4. Nitritas: nitritas nėra įprastas žmogaus šlapimo komponentas. Tačiau, šlapime aptinkamas nitritas gali indikuoti apie šlapimo takų infekcijas ar bakterines infekcijas. > 20 mg/dL nitrito kiekis gali įtakoti klaidingai teigiamo glutaraldehido rezultato atsiradimą.
5. Glutaraldehidas paprastai nėra aptinkamas šlapime. Tačiau tam tikri metaboliniai sutrikimai, pvz., ketoacidozė (badavimas, negydomas diabetas, baltyminė dieta) gali interferuoti tyrimo rezultatus.
6. Kreatininas: normalus kreatinino lygis yra nuo 20 iki 350 mg/dL. Retais atvejais, tam tikros inkstų ligos gali sukelti teigiamo šlapimo skiedimo rezultato atsiradimą.
7. Baliklis: normaliame žmogaus šlapime baliklis nėra aptinkamas. Didelis baliklio kiekis mėginyje gali sukelti klaidingai neigiamą baliklio testo laukelio rezultatą.

【TIKĖTINOS REIKŠMĖS】

Neigiamas rezultatas reiškia, jog narkotinių medžiagų koncentracija yra žemiau aptinkamo lygio. Teigiamas rezultatas reiškia, jog narkotinių medžiagų koncentracija yra aukštesnė nei aptinkamas kiekis.

【VEIKSMINGUMO CHARAKTERISTIKA】

Tikslumas

Buvo atliekama lyginamoji studija, naudojant Multi-Drug greito testo panelį ir komerciškai įsigytus greitus narkotinių medžiagų testus. Tyrimas buvo atliekamas naudojant apie 250 mėginių narkotinių medžiagų tipui su šlapimu, surinktu iš asmenų, dalyvavusių narkotinių medžiagų skryningo tyrime. Numanomai teigiami mėginiai buvo patvirtinti atliekant GC/MS.

Metodas		GC/MS		% atitikimas su GC/MS
Multi-Drug greito testo panelis		Teigiamas	Neigiamas	
ACE 5,000	Teigiamas	29	1	93.5%
	Neigiamas	2	68	98.6%
AMP 1,000	Teigiamas	103	3	98.1%
	Neigiamas	2	142	97.9%
AMP 500	Teigiamas	110	2	99.1%
	Neigiamas	1	137	98.6%
AMP 300	Teigiamas	116	2	99.1%
	Neigiamas	1	131	98.5%
BAR 300	Teigiamas	98	2	96.1%
	Neigiamas	4	146	98.6%
BAR 200	Teigiamas	101	3	95.3%
	Neigiamas	5	141	97.9%
BZO	Teigiamas	112	3	98.2%

Metodas		GC/MS		% atitikimas su GC/MS
Multi-Drug greito testo panelis		Teigiamas	Neigiamas	
500	Neigiamas	2	133	97.8%
BZO 300	Teigiamas	121	1	98.4%
	Neigiamas	2	126	99.2%
BZO 200	Teigiamas	127	2	99.2%
	Neigiamas	1	120	98.4%
BZO 100	Teigiamas	128	3	99.2%
	Neigiamas	1	118	97.5%
BUP 10	Teigiamas	105	0	99.1%
	Neigiamas	1	144	>99.9%
BUP 5	Teigiamas	105	0	99.1%
	Neigiamas	1	144	>99.9%
COC 300	Teigiamas	111	3	98.2%
	Neigiamas	2	134	97.8%
COC 200	Teigiamas	40	0	>99.9%
	Neigiamas	0	60	>99.9%
COC 150	Teigiamas	116	4	98.3%
	Neigiamas	2	128	97.0%
COC 100	Teigiamas	117	4	99.2%
	Neigiamas	1	128	97.0%
THC 300	Teigiamas	85	3	95.5%
	Neigiamas	4	158	98.1%
THC 200	Teigiamas	85	4	93.4%
	Neigiamas	6	155	97.5%
THC 150	Teigiamas	86	4	94.5%
	Neigiamas	5	155	97.5%
THC 50	Teigiamas	92	3	97.9%
	Neigiamas	2	153	98.1%
THC 30	Teigiamas	94	3	97.9%
	Neigiamas	2	151	98.1%
THC 25	Teigiamas	95	4	96.9%
	Neigiamas	3	148	97.4%
MTD 300	Teigiamas	89	2	98.9%
	Neigiamas	1	158	98.8%
MTD 200	Teigiamas	91	2	98.7%
	Neigiamas	1	156	98.7%
MET 1,000	Teigiamas	76	5	96.2%
	Neigiamas	3	166	97.1%
MET 500	Teigiamas	83	5	97.6%
	Neigiamas	2	160	97.0%
MET 300	Teigiamas	88	4	97.8%
	Neigiamas	2	156	97.5%
MDMA 1,000	Teigiamas	99	1	98.0%
	Neigiamas	2	148	99.3%
MDMA 500	Teigiamas	102	1	98.1%
	Neigiamas	2	145	99.3%
MDMA 300	Teigiamas	103	1	98.1%
	Neigiamas	2	144	99.3%
MOP 300	Teigiamas	95	7	95.0%
	Neigiamas	5	143	95.3%
MOP 200	Teigiamas	95	6	95.0%
	Neigiamas	5	144	96.0%
MOP 100	Teigiamas	98	5	97.0%
	Neigiamas	3	144	96.6%
MQL	Teigiamas	79	11	89.8%
	Neigiamas	9	151	93.2%
OPI	Teigiamas	117	8	96.7%
	Neigiamas	4	121	93.8%
PCP	Teigiamas	85	5	92.4%
	Neigiamas	7	153	96.8%
PPX	Teigiamas	97	9	96.0%
	Neigiamas	4	140	94.0%
TCA	Teigiamas	91	13	94.8%
	Neigiamas	5	141	91.6%
TML 100	Teigiamas	82	12	88.2%
	Neigiamas	11	145	92.4%
TML 200	Teigiamas	82	6	88.2%
	Neigiamas	11	151	96.2%
TML 300	Teigiamas	81	6	88.0%
	Neigiamas	11	152	96.2%
KET 1,000	Teigiamas	77	3	97.5%
	Neigiamas	2	168	98.2%
KET 500	Teigiamas	81	3	97.6%
	Neigiamas	2	164	98.2%
KET 300	Teigiamas	89	4	96.7%
	Neigiamas	3	154	97.5%
KET 100	Teigiamas	97	4	96.0%
	Neigiamas	4	145	97.3%
OXY 100	Teigiamas	84	1	97.7%
	Neigiamas	2	163	99.4%
COT 200	Teigiamas	88	4	96.7%
	Neigiamas	3	155	97.5%
COT 100	Teigiamas	93	3	97.9%
	Neigiamas	2	152	98.1%
EDDP	Teigiamas	92	1	97.9%

Metodas		GC/MS		% atitikimas su GC/MS
Multi-Drug greito testo panelis		Teigiamas	Neigiamas	
300	Neigiamas	2	155	99.4%
EDDP 100	Teigiamas	95	5	96.9%
	Neigiamas	3	147	96.7%
FYL 20	Teigiamas	79	1	98.8%
	Neigiamas	1	169	99.4%
FYL 10	Teigiamas	80	1	98.8%
	Neigiamas	1	168	99.4%
K2-50	Teigiamas	78	3	97.5%
	Neigiamas	2	167	98.2%
K2-30	Teigiamas	82	2	97.6%
	Neigiamas	2	164	98.8%
K2-25	Teigiamas	82	3	97.6%
	Neigiamas	2	163	98.2%
6-MAM10	Teigiamas	42	2	97.7%
	Neigiamas	1	105	98.1%
MDA500	Teigiamas	103	3	98.1%
	Neigiamas	2	142	97.9%
ETG500	Teigiamas	83	1	97.6%
	Neigiamas	2	164	99.4%
ETG1,000	Teigiamas	81	1	95.3%
	Neigiamas	4	164	99.4%
CLO 400	Teigiamas	101	1	97.1%
	Neigiamas	3	145	99.3%
CLO 150	Teigiamas	103	2	99.0%
	Neigiamas	1	144	98.6%
LSD 20	Teigiamas	33	1	94.3%
	Neigiamas	2	64	98.5%
LSD 50	Teigiamas	32	1	94.1%
	Neigiamas	2	65	98.5%
MPD	Teigiamas	35	1	94.6%
	Neigiamas	2	62	98.4%
ZOL	Teigiamas	20	2	90.9%
	Neigiamas	2	66	97.1%
MEP100	Teigiamas	19	2	90.5%
	Neigiamas	2	64	97.0%
MDPV1000	Teigiamas	28	1	93.3%
	Neigiamas	2	69	98.6%
MDPV 500	Teigiamas	27	1	93.1%
	Neigiamas	2	59	98.3%
DIA 300	Teigiamas	121	1	98.4%
	Neigiamas	2	126	99.2%
DIA 200	Teigiamas	121	1	98.4%
	Neigiamas	2	126	99.2%
ZOP 50	Teigiamas	19	2	86.4%
	Neigiamas	3	69	97.2%
MCAT 500	Teigiamas	20	4	90.9%
	Neigiamas	2	76	95.0%
7-ACL 300	Teigiamas	32	1	94.1%
	Neigiamas	2	43	97.7%
7-ACL 200	Teigiamas	35	1	94.6%
	Neigiamas	2	40	97.6%
7-ACL 100	Teigiamas	36	1	94.7%
	Neigiamas	2	39	97.5%
CFYL 500	Teigiamas	36	1	94.7%
	Neigiamas	2	72	98.6%
CAF 1000	Teigiamas	21	3	91.3%
	Neigiamas	2	66	95.7%
CAT 150	Teigiamas	19	2	90.5%
	Neigiamas	2	73	97.3%
TRO 350	Teigiamas	23	2	92.0%
	Neigiamas	2	64	97.0%
ALP 100	Teigiamas	20	2	90.9%
	Neigiamas	2	74	97.4%
ABP 10	Teigiamas	23	2	92.0%
	Neigiamas	2	68	97.1%

% Atitikimas su komerciškai įsigytu rinkiniu

	ACE 5,000	AMP 1,000	AMP 500	AMP 300	BAR 300	BAR 200	BZO 500	BZO 300	BZO 200	BZO 100	BUP 10
Teigiamas Atitikimas	*	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%
Neigiamas Atitikimas	*	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%
Bendri rezultatai	*	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%

	BUP 5	COC 300	COC 200	COC 150	COC 100	THC 150	THC 50	THC 25	MTD 300	MTD 200	MET 1,000
Teigiamas Atitikimas	*	>99.9%	*	*	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%
Neigiamas Atitikimas	*	>99.9%	*	*	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%
Bendri rezultatai	*	>99.9%	*	*	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%

	MET 500	MET 300	MDMA 1,000	MDMA 500	MDMA 300	MOP 300	MOP 100	MQL	OPI	PCP	PPX
Teigiamas Atitikimas	>99.9%	>99.9%	>99.9%	>99.9%	*	>99.9%	>99.9%	>99.9%	*	>99.9%	>99.9%
Neigiamas Atitikimas	>99.9%	>99.9%	>99.9%	>99.9%	*	>99.9%	>99.9%	>99.9%	*	>99.9%	>99.9%
Bendri rezultatai	>99.9%	>99.9%	>99.9%	>99.9%	*	>99.9%	>99.9%	>99.9%	*	>99.9%	>99.9%

	TCA	TML 100	TML 200	TML 300	KET 1,000	KET 500	KET 300	KET 100	OXY	COT 200	COT 100
Teigiamas Atitikimas	*	*	*	*	>99.9%	>99.9%	>99.9%	>99.9%	*	*	*
Neigiamas Atitikimas	*	*	*	*	>99.9%	>99.9%	>99.9%	>99.9%	*	*	*
Bendri rezultatai	*	*	*	*	>99.9%	>99.9%	>99.9%	>99.9%	*	*	*

	EDDP 300	EDDP 100	FYL 20	FYL 10	K2 50	K2 30	K5 25	6-MAM 10	MDA 500	ETG 500	ETG 1,000	CLO 400
Teigiamas Atitikimas	*	*	*	*	*	*	*	*	*	*	*	*
Neigiamas Atitikimas	*	*	*	*	*	*	*	*	*	*	*	*
Bendri rezultatai	*	*	*	*	*	*	*	*	*	*	*	*

	CLO 150	LSD 20	LSD 50	MPD	ZOL	THC 200	THC 30/30 0	MOP 200	MEP 100	MDP V 1000	DIA 300	DIA 200	ZOP 50	MCA T 500
Teigiamas Atitikimas	*	*	*	*	*	>99.9 %	*	*	*	*	*	*	*	*
Neigiamas Atitikimas	*	*	*	*	*	>99.9 %	*	*	*	*	*	*	*	*
Bendri rezultatai	*	*	*	*	*	>99.9 %	*	*	*	*	*	*	*	*

	7-ACL 300	7-ACL 200	7-ACL 100	CFYL 500	CAF 1000	CAT 150	TRO 350	ALP	MDPV 500	ABP 10
Teigiamas Atitikimas	*	*	*	*	*	*	*	*	*	*
Neigiamas Atitikimas	*	*	*	*	*	*	*	*	*	*
Bendri rezultatai	*	*	*	*	*	*	*	*	*	*

* Pastaba: remiantis GC/MS duomenimis vietoje komerciškai įsigyto rinkinio.

Preciziškumas

Studija buvo atliekama trijose ligoninėse, naudojant tris skirtingas produkto partijas dėl preciziškumo tyrimo ribose, tarp tyrimų ir tarp operatorių nustatymo. Identiška koduotų mėginių kortelė su narkotinėmis medžiagomis ties slenkstinių verčių koncentracijomis ± 50% ir ±25%, buvo pažymėtos, užkoduotos ir tirtos kiekvienoje vietoje. Rezultatai pateikiami žemiau:

ACETAMINOPHEN (ACE5,000)

Amphetamine konc. (ng/mL)	n vietoje	Vieta A		Vieta B		Vieta C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
2,500	10	10	0	10	0	10	0
3,750	10	9	1	9	1	8	2
6,250	10	1	9	1	9	1	9
7,500	10	0	10	0	10	0	10

AMPHETAMINE (AMP 1,000)

Amphetamine konc.(ng/mL)	n vietoje	Vieta A		Vieta B		Vieta C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
500	10	10	0	10	0	10	0
750	10	9	1	8	2	9	1
1,250	10	1	9	2	8	2	8
1,500	10	0	10	0	10	0	10

AMPHETAMINE (AMP 500)

Amphetamine konc.(ng/mL)	n vietoje	Vieta A		Vieta B		Vieta C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
250	10	10	0	10	0	10	0
375	10	9	1	9	1	9	1
625	10	2	8	1	9	2	8
750	10	0	10	0	10	0	10

AMPHETAMINE (AMP 300)

Amphetamine konc.(ng/mL)	n vietoje	Vieta A		Vieta B		Vieta C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
150	10	10	0	10	0	10	0
225	10	8	2	8	2	8	2
375	10	2	8	2	8	2	8
450	10	0	10	0	10	0	10

BARBITURATES (BAR 300)

Secobarbital konc.(ng/mL)	n vietoje	Vieta A		Vieta B		Vieta C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
150	10	10	0	10	0	10	0
225	10	9	1	8	2	9	1
375	10	2	8	1	9	2	8
450	10	0	10	0	10	0	10

BARBITURATES (BAR 200)

Secobarbital konc.(ng/mL)	n vietoje	Vieta A		Vieta B		Vieta C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
100	10	10	0	10	0	10	0
150	10	9	1	9	1	9	1
250	10	1	9	1	9	1	9
300	10	0	10	0	10	0	10

BENZODIAZEPINES (BZO 500)

Oxazepam konc.(ng/mL)	n vietoje	Vieta A		Vieta B		Vieta C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
250	10	10	0	10	0	10	0
375	10	8	2	9	1	8	2
625	10	1	9	2	8	1	9
750	10	0	10	0	10	0	10

BENZODIAZEPINES (BZO 300)

Oxazepam konc.(ng/mL)	n vietoje	Vieta A		Vieta B		Vieta C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
150	10	10	0	10	0	10	0
225	10	9	1	9	1	9	1
375	10	1	9	1	9	1	9
450	10	0	10	0	10	0	10

BENZODIAZEPINES (BZO 200)

Oxazepam konc.(ng/mL)	n vietoje	Vieta A		Vieta B		Vieta C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
100	10	10	0	10	0	10	0
150	10	9	1	8	2	9	1
250	10	1	9	1	9	2	8
300	10	0	10	0	10	0	10

BENZODIAZEPINES (BZO 100)

Oxazepam konc.(ng/mL)	n vietoje	Vieta A		Vieta B		Vieta C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
50	10	10	0	10	0	10	0
75	10	9	1	8	2	7	3
125	10	1	9	1	9	2	8
150	10	0	10	0	10	0	10

BUPRENORPHINE (BUP 10)

Buprenorphine konc.(ng/mL)	n vietoje	Vieta A		Vieta B		Vieta C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
5	10	10	0	10	0	10	0
7.5	10	9	1	9	1	8	2
12.5	10	1	9	1	9	1	9
15	10	0	10	0	10	0	10

BUPRENORPHINE (BUP 5)

Buprenorphine konc.(ng/mL)	n vietoje	Vieta A		Vieta B		Vieta C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
2.5	10	10	0	10	0	10	0
3.75	10	9	1	9	1	8	2
6.25	10	1	9	1	9	1	9
7.5	10	0	10	0	10	0	10

COCAINE (COC 300)

Benzoylecgonine konc.(ng/mL)	n vietoje	Vieta A		Vieta B		Vieta C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
150	10	10	0	10	0	10	0
225	10	9	1	9	1	9	1
375	10	1	9	1	9	1	9
450	10	0	10	0	10	0	10

COCAINE (COC 200)

Benzoylecgonine konc.(ng/mL)	n vietoje	Vieta A		Vieta B		Vieta C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
100	10	10	0	10	0	10	0
150	10	9	1	9	1	9	1
250	10	1	9	1	9	1	9
300	10	0	10	0	10	0	10

COCAINE (COC 150)

Benzoylecgonine konc.(ng/mL)	n vietoje	Vieta A		Vieta B		Vieta C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
75	10	10	0	10	0	10	0
112.5	10	9	1	9	1	9	1
187.5	10	2	8	2	8	2	8
225	10	0	10	0	10	0	10

COCAINE (COC 100)

Benzoylecgonine konc.(ng/mL)	n vietoje	Vieta A		Vieta B		Vieta C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
50	10	10	0	10	0	10	0
75	10	9	1	9	1	9	1
125	10	2	8	2	8	2	8
150	10	0	10	0	10	0	10

MARIJUANA (THC300)

11-nor-∆9-THC-9 COOH Concentration (ng/mL)	n vietoje	Vieta A		Vieta B		Vieta C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
150	10	10	0	10	0	10	0
225	10	8	2	9	1	9	1
375	10	2	8	3	7	1	9
450	10	0	10	0	10	0	10

MARIJUANA (THC200)

11-nor-Δ^9-COOH konc.(ng/mL)	n vietoje	Vieta A		Vieta B		Vieta C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
100	10	10	0	10	0	10	0
150	10	9	1	9	1	9	1
250	10	2	8	1	9	1	9
300	10	0	10	0	10	0	10

MARIJUANA (THC150)

11-nor-Δ^9-COOH konc.(ng/mL)	n vietoje	Vieta A		Vieta B		Vieta C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
75	10	10	0	10	0	10	0
112.5	10	9	1	9	1	9	1
187.5	10	2	8	1	9	1	9
225	10	0	10	0	10	0	10

MARIJUANA (THC50)

11-nor-Δ^9-COOH konc.(ng/mL)	n vietoje	Vieta A		Vieta B		Vieta C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
25	10	10	0	10	0	10	0
37.5	10	9	1	8	2	9	1
62.5	10	1	9	1	9	2	8
75	10	0	10	0	10	0	10

MARIJUANA (THC25)

11-nor-Δ^9-COOH konc.(ng/mL)	n vietoje	Vieta A		Vieta B		Vieta C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
12.5	10	10	0	10	0	10	0
18.75	10	8	2	8	2	8	2
31.25	10	1	9	1	9	2	8
37.5	10	0	10	0	10	0	10

MARIJUANA (THC30)

11-nor-Δ^9-COOH konc.(ng/mL)	n vietoje	Vieta A		Vieta B		Vieta C	
		-	+	-	-	+	-
0	10	10	0	10	0	10	0
15	10	10	0	10	0	10	0
22.5	10	9	1	9	1	9	1
37.5	10	2	8	2	8	1	9
45	10	0	10	0	10	0	10

METHADONE (MTD300)

Methadone konc.(ng/mL)	n vietoje	Vieta A		Vieta B		Vieta C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
150	10	10	0	10	0	10	0
225	10	9	1	9	1	9	1
375	10	1	9	1	9	1	9
450	10	0	10	0	10	0	10

METHADONE (MTD200)

Methadone konc.(ng/mL)	n vietoje	Vieta A		Vieta B		Vieta C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
100	10	10	0	10	0	10	0
150	10	8	2	8	2	8	2
250	10	1	9	1	9	2	8
300	10	0	10	0	10	0	10

METHAMPHETAMINE (MET1,000)

Methamphetamine konc.(ng/mL)	n vietoje	Vieta A		Vieta B		Vieta C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
500	10	10	0	10	0	10	0
750	10	9	1	9	1	9	1
1,250	10	1	9	2	8	1	9
1,500	10	0	10	0	10	0	10

METHAMPHETAMINE (MET 500)

Methamphetamine konc.(ng/mL)	n vietoje	Vieta A		Vieta B		Vieta C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
250	10	10	0	10	0	10	0
375	10	9	1	9	1	9	1
625	10	1	9	1	9	1	9
750	10	0	10	0	10	0	10

METHAMPHETAMINE (MET300)

Methamphetamine konc.(ng/mL)	n vietoje	Vieta A		Vieta B		Vieta C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
150	10	10	0	10	0	10	0
225	10	9	1	9	1	9	1
375	10	1	9	1	9	1	9
450	10	0	10	0	10	0	10

METHYLENEDIOXYMETHAMPHETAMINE (MDMA1, 000) Ecstasy

Methylenedioxymethamphetamine konc.(ng/mL)	n vietoje	Vieta A		Vieta B		Vieta C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
500	10	10	0	10	0	10	0
750	10	9	1	9	1	8	2
1,250	10	1	9	1	9	1	9
1,500	10	0	10	0	10	0	10

METHYLENEDIOXYMETHAMPHETAMINE (MDMA 500) Ecstasy

Methylenedioxymethamphetamine konc.(ng/mL)	n vietoje	Vieta A		Vieta B		Vieta C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
250	10	10	0	10	0	10	0
375	10	8	2	9	1	9	1
625	10	1	9	1	9	1	9
750	10	0	10	0	10	0	10

METHYLENEDIOXYMETHAMPHETAMINE (MDMA 300) Ecstasy

Methylenedioxymethamphetamine konc.(ng/mL)	n vietoje	Vieta A		Vieta B		Vieta C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
250	10	10	0	10	0	10	0
375	10	8	2	9	1	7	3
625	10	2	8	1	9	1	9
750	10	0	10	0	10	0	10

MORPHINE (MOP 300)

Morphine konc.(ng/mL)	n vietoje	Vieta A		Vieta B		Vieta C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
150	10	10	0	10	0	10	0
225	10	9	1	9	1	9	1
375	10	1	9	1	9	1	9
450	10	0	10	0	10	0	10

MORPHINE (MOP 200)

Morphine konc.(ng/mL)	n vietoje	Vieta A		Vieta B		Vieta C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
100	10	10	0	10	0	10	0
150	10	7	3	9	1	9	1
250	10	1	9	2	8	1	9
300	10	0	10	0	10	0	10

MORPHINE (MOP 100)

Morphine konc.(ng/mL)	n vietoje	Vieta A		Vieta B		Vieta C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
50	10	10	0	10	0	10	0
75	10	9	1	9	1	9	1
125	10	1	9	1	9	1	9
150	10	0	10	0	10	0	10

METHAQUALONE (MQL 300)

Methaqualone konc.(ng/mL)	n vietoje	Vieta A		Vieta B		Vieta C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
150	10	10	0	10	0	10	0
225	10	9	1	9	1	9	1
375	10	1	9	1	9	1	9
450	10	0	10	0	10	0	10

MORPHINE/OPIATE (OPI 2,000)

Morphine konc.(ng/mL)	n vietoje	Vieta A		Vieta B		Vieta C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
1,000	10	10	0	10	0	10	0
1,500	10	9	1	9	1	9	1
2,500	10	1	9	1	9	1	9
3,000	10	0	10	0	10	0	10

PHENCYCLIDINE (PCP)

Phencyclidine konc.(ng/mL)	n vietoje	Vieta A		Vieta B		Vieta C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
12.5	10	10	0	10	0	10	0
18.75	10	8	2	9	1	9	1
31.25	10	1	9	1	9	1	9
37.5	10	0	10	0	10	0	10

PROPOXYPHENE (PPX)

Propoxyphene konc.(ng/mL)	n vietoje	Vieta A		Vieta B		Vieta C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
150	10	10	0	10	0	10	0
225	10	8	2	9	1	9	1
375	10	1	9	1	9	1	9
450	10	0	10	0	10	0	10

TRICYCLIC ANTIDEPRESSANTS (TCA)

Nortriptyline konc.(ng/mL)	n vietoje	Vieta A		Vieta B		Vieta C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
500	10	10	0	10	0	10	0
750	10	9	1	8	2	8	2
1,250	10	1	9	1	9	1	9
1,500	10	0	10	0	10	0	10

TRAMADOL (TML 100)

Tramadol konc.(ng/mL)	n vietoje	Vieta A		Vieta B		Vieta C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
50	10	10	0	10	0	10	0
75	10	9	1	9	1	8	2
125	10	1	9	1	9	2	8
150	10	0	10	0	10	0	10

TRAMADOL (TML 200)

Tramadol konc.(ng/mL)	n vietoje	Vieta A		Vieta B		Vieta C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
100	10	10	0	10	0	10	0
150	10	9	1	9	1	8	2
250	10	1	9	1	9	2	8
300	10	0	10	0	10	0	10

TRAMADOL (TML 300)

Tramadol konc.(ng/mL)	n vietoje	Vieta A		Vieta B		Vieta C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
150	10	10	0	10	0	10	0
225	10	9	1	9	1	8	2
375	10	1	9	1	9	2	8
450	10	0	10	0	10	0	10

KETAMINE (KET1, 000)

Ketamine konc.(ng/mL)	n vietoje	Vieta A		Vieta B		Vieta C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
500	10	10	0	10	0	10	0
750	10	9	1	8	2	9	1
1,250	10	1	9	1	9	2	8
1,500	10	0	10	0	10	0	10

KETAMINE (KET500)

Ketamine konc.(ng/mL)	n vietoje	Vieta A		Vieta B		Vieta C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
250	10	10	0	10	0	10	0
375	10	9	1	9	1	8	2
625	10	1	9	1	9	2	8
750	10	0	10	0	10	0	10

KETAMINE (KET300)

Ketamine konc.(ng/mL)	n vietoje	Vieta A		Vieta B		Vieta C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
150	10	10	0	10	0	10	0
225	10	9	1	9	1	9	1
375	10	1	9	1	9	1	9
450	10	0	10	0	10	0	10

KETAMINE (KET100)

Ketamine konc.(ng/mL)	n vietoje	Vieta A		Vieta B		Vieta C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
50	10	10	0	10	0	10	0
75	10	9	1	9	1	9	1
125	10	1	9	1	9	2	8
150	10	0	10	0	10	0	10

OXYCODONE (OXY100)

Oxycodone konc.(ng/mL)	n vietoje	Vieta A		Vieta B		Vieta C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
50	10	10	0	10	0	10	0
75	10	9	1	9	1	9	1
125	10	1	9	1	9	1	9
150	10	0	10	0	10	0	10

COTININE (COT 200)

Cotinine konc.(ng/mL)	n vietoje	Vieta A		Vieta B		Vieta C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
100	10	10	0	10	0	10	0
150	10	9	1	9	1	9	1
250	10	1	9	1	9	2	8
300	10	0	10	0	10	0	10

COTININE (COT 100)

Cotinine konc.(ng/mL)	n vietoje	Vieta A		Vieta B		Vieta C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
50	10	10	0	10	0	10	0
75	10	9	1	9	1	9	1
125	10	1	9	1	9	1	9
150	10	0	10	0	10	0	10

2-ETHYLIDENE-1,5-DIMETHYL-3,3-DIPHENYLPYRROLIDINE (EDDP 300)

EDDP konc.(ng/mL)	n vietoje	Vieta A		Vieta B		Vieta C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
150	10	10	0	10	0	10	0
225	10	9	1	9	1	9	1
375	10	1	9	2	8	1	9
450	10	0	10	0	10	0	10

2-ETHYLIDENE-1,5-DIMETHYL-3,3-DIPHENYLPYRROLIDINE (EDDP 100)

EDDP konc.(ng/mL)	n vietoje	Vieta A		Vieta B		Vieta C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
50	10	10	0	10	0	10	0
75	10	9	1	9	1	9	1
125	10	1	9	1	9	1	9
150	10	0	10	0	10	0	10

FENTANYL (FYL20)

FYL konc.(ng/mL)	n vietoje	Vieta A		Vieta B		Vieta C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
10	10	10	0	10	0	10	0
15	10	9	1	9	1	9	1
25	10	1	9	1	9	1	9
30	10	0	10	0	10	0	10

FENTANYL (FYL10)

FYL konc.(ng/mL)	n vietoje	Vieta A		Vieta B		Vieta C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
5	10	10	0	10	0	10	0
7.5	10	9	1	9	1	9	1
12.5	10	1	9	1	9	1	9
15	10	0	10	0	10	0	10

K2 50

K2 konc.(ng/mL)	n vietoje	Vieta A		Vieta B		Vieta C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
25	10	10	0	10	0	10	0
37.5	10	8	2	8	2	9	1
62.5	10	1	9	2	8	2	8
75	10	0	10	0	10	0	10

K2 30

K2 konc.(ng/mL)	n vietoje	Vieta A		Vieta B		Vieta C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
15	10	10	0	10	0	10	0
22.5	10	8	2	9	1	9	1
37.5	10	1	9	1	9	1	9
45	10	0	10	0	10	0	10

K2 25

K2 konc.(ng/mL)	n vietoje	Vieta A		Vieta B		Vieta C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
12.5	10	10	0	10	0	10	0
18.75	10	7	3	8	2	8	2
31.25	10	1	9	1	9	2	8
37.5	10	0	10	0	10	0	10

6-MAM

6-MAM konc.(ng/mL)	n vietoje	Vieta A		Vieta B		Vieta C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
5	10	10	0	10	0	10	0
7.5	10	9	1	9	1	9	1
12.5	10	1	9	1	9	1	9
15	10	0	10	0	10	0	10

MDA 500

MDA konc.(ng/mL)	n vietoje	Vieta A		Vieta B		Vieta C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
250	10	10	0	10	0	10	0
375	10	9	1	9	1	9	1
625	10	1	9	1	9	1	9
750	10	0	10	0	10	0	10

ETG500

Ethyl Glucuronide konc.((ng/mL)	n vietoje	Vieta A		Vieta B		Vieta C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
250	10	10	0	10	0	10	0
375	10	8	2	8	2	9	1
625	10	1	9	2	8	2	8
750	10	0	10	0	10	0	10

ETG1,000

Ethyl Glucuronide konc.((ng/mL)	n vietoje	Vieta A		Vieta B		Vieta C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
500	10	10	0	10	0	10	0
750	10	8	2	8	2	9	1
1250	10	1	9	2	8	2	8
1500	10	0	10	0	10	0	10

CLO 400

Clonazepam konc.((ng/mL)	n vietoje	Vieta A		Vieta B		Vieta C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
200	10	10	0	10	0	10	0
300	10	9	1	8	2	9	1
500	10	1	9	2	8	1	9
600	10	0	10	0	10	0	10

CLO 150

Clonazepam konc.((ng/mL)	n vietoje	Vieta A		Vieta B		Vieta C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
75	10	10	0	10	0	10	0
112	10	9	1	8	2	9	1
187	10	1	9	2	8	1	9
225	10	0	10	0	10	0	10

LSD 20

Clonazepam konc.((ng/mL)	n vietoje	Vieta A		Vieta B		Vieta C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
10	10	10	0	10	0	10	0
15	10	9	1	9	1	9	1
25	10	1	9	1	9	1	9
30	10	0	10	0	10	0	10

LSD 50

Clonazepam konc.((ng/mL)	n vietoje	Vieta A		Vieta B		Vieta C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
25	10	10	0	10	0	10	0
37.5	10	9	1	9	1	9	1
62.5	10	1	9	1	9	1	9
75	10	0	10	0	10	0	10

MPD

Methylphenidate (Ritalin) konc.((ng/mL)	n vietoje	Vieta A		Vieta B		Vieta C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
150	10	10	0	10	0	10	0
225	10	9	1	8	2	9	1
375	10	1	9	2	8	1	9
450	10	0	10	0	10	0	10

ZOL

Zolpidem konc.((ng/mL)	n vietoje	Vieta A		Vieta B		Vieta C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
25	10	9	1	10	0	10	0
75	10	0	10	1	9	0	10

MEPHEDRONE (MEP 100)

Mephedrone HCl konc.((ng/mL)	n vietoje	Vieta A		Vieta B		Vieta C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
50	10	10	0	10	0	10	0
75	10	9	1	8	2	9	1
125	10	2	8	2	8	2	8
150	10	0	10	0	10	0	10

3, 4-METHYLENEDIOXYPYROVALERONE (MDPV1000)

3, 4-methylenedioxypyrovalerone konc.((ng/mL)	n vietoje	Vieta A		Vieta B		Vieta C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
500	10	10	0	10	0	10	0
750	10	9	1	9	1	8	2
1250	10	1	9	1	9	1	9
1500	10	0	10	0	10	0	10

3, 4-METHYLENEDIOXYPYROVALERONE (MDPV500)

3, 4-methylenedioxypyrovalerone konc.((ng/mL)	n vietoje	Vieta A		Vieta B		Vieta C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
250	10	10	0	10	0	10	0
375	10	9	1	9	1	8	2
625	10	2	8	1	9	1	9
750	10	0	10	0	10	0	10

DIAZEPAM (DIA 300)

Diazepam konc.((ng/mL)	n vietoje	Vieta A		Vieta B		Vieta C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
150	10	10	0	10	0	10	0
225	10	9	1	9	1	9	1
375	10	1	9	1	9	1	9
450	10	0	10	0	10	0	10

DIAZEPAM (DIA 200)

Diazepam konc.((ng/mL)	n vietoje	Vieta A		Vieta B		Vieta C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
100	10	10	0	10	0	10	0
150	10	9	1	9	1	9	1
250	10	1	9	1	9	1	9
300	10	0	10	0	10	0	10

ZOPICLONE (ZOP 50)

Zopiclone konc.(ng/mL)	n vietoje	Vieta A		Vieta B		Vieta C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
25	10	10	0	10	0	10	0
37.5	10	9	1	8	2	9	1
62.5	10	2	8	2	8	2	8
75	10	0	10	0	10	0	10

METHCATHINONE (MCAT 500)

Methcathinone konc.(ng/mL)	n vietoje	Vieta A		Vieta B		Vieta C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
250	10	10	0	10	0	10	0
375	10	9	1	8	2	9	1
625	10	2	8	2	8	2	8
750	10	0	10	0	10	0	10

7-ACL(300)

7- Aminoclonazepam konc. (ng/mL)	n vietoje	Vieta A		Vieta B		Vieta C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
150	10	10	0	10	0	10	0
225	10	8	2	9	1	9	1
375	10	2	8	2	8	3	7
450	10	0	10	0	10	0	10

7-ACL(200)

7- Aminoclonazepam konc.(ng/mL)	n vietoje	Vieta A		Vieta B		Vieta C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
100	10	10	0	10	0	10	0
150	10	8	2	9	1	8	2
250	10	2	8	2	8	2	8
300	10	0	10	0	10	0	10

7-ACL(100)

7- Aminoclonazepam konc.(ng/mL)	n vietoje	Vieta A		Vieta B		Vieta C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
50	10	10	0	10	0	10	0
75	10	7	3	7	3	9	1
125	10	2	8	1	9	2	8
150	10	0	10	0	10	0	10

CARFENTANYL(CFYL500)

Carfentanyl konc.(ng/mL)	n vietoje	Vieta A		Vieta B		Vieta C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
250	10	10	0	10	0	10	0
375	10	7	3	9	1	8	2
625	10	2	8	1	9	2	8
750	10	0	10	0	10	0	10

CAFFEINE (CAF 1000)

Caffeine konc.(ng/mL)	n vietoje	Vieta A		Vieta B		Vieta C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
500	10	10	0	10	0	10	0
750	10	9	1	8	2	9	1
1250	10	2	8	2	8	2	8
1500	10	0	10	0	10	0	10

CATHINE (CAT 150)

(+)-Norpseudoephedrine HCl konc.(ng/mL)	n vietoje	Vieta A		Vieta B		Vieta C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
75	10	10	0	10	0	10	0
112.5	10	9	1	8	2	9	1
187.5	10	2	8	2	8	2	8
225	10	0	10	0	10	0	10

TROPICAMIDE (TRO)

Tropicamide konc. (ng/ml)	n vietoje	Vieta A		Vieta B		Vieta C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
175	10	10	0	10	0	10	0
262.5	10	8	2	8	2	8	2
437.5	10	2	8	2	8	2	8
525	10	0	10	0	10	0	10

ALPRAZOLAM（ALP）

Alprazolam konc. (ng/ml)	n vietoje	Vieta A		Vieta B		Vieta C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
50	10	10	0	10	0	10	0
75	10	10	0	10	0	10	0
125	10	9	1	8	2	9	1
150	10	2	8	2	8	2	8

AB-PINACA (ABP10)

AB-PINACA konc. (ng/mL)	n vietoje	Vieta A		Vieta B		Vieta C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
5	10	10	0	10	0	10	0
7.5	10	8	2	8	2	9	1
12.5	10	2	8	3	7	1	9
15	10	0	10	0	10	0	10

Analitinis jautrumas

Į puluotą šlapimą be narkotikų buvo pridėta narkotinių medžiagų nurodytomis koncentracijomis. Rezultatai yra pateikiami lentelėse žemiau.

Nark.medž.koncentracija Slenkstinės ribos	ACE 5000		AMP 1,000		AMP500		AMP 300		BAR 300		BAR 200		BZO500		BZO300	
	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
0% Slenkst.v.	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-50% Slenkst.v.	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-25% Slenkst.v.	26	4	26	4	25	5	27	3	27	3	26	4	27	3	27	3
Slenkst.v.	14	16	15	15	15	15	15	15	16	14	15	15	15	15	15	15
+25% Slenkst.v.	3	27	3	27	3	27	4	26	4	26	3	27	4	26	3	27
+50% Slenkst.v.	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30
+300% Slenkst.v.	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30

Nark.medž.koncentracija Slenkstinės ribos	BZO200		BZO100		BUP 10		BUP 5		COC300		COC 200		COC 150		COC100	
	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
0% Slenkst.v.	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-50% Slenkst.v.	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-25% Slenkst.v.	27	3	27	3	26	4	26	4	26	4	26	4	27	3	27	3
Slenkst.v.	16	14	14	16	14	16	14	16	13	17	14	16	16	14	16	14
+25% Slenkst.v.	3	27	3	27	3	27	3	27	3	27	3	27	4	26	4	26
+50% Slenkst.v.	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30
+300% Slenkst.v.	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30

Nark.medž.koncentracija Slenkstinės ribos	THC150		THC50		THC25		MTD300		MTD200		MET 1,000		MET500		MET300	
	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
0% Slenkst.v.	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-50% Slenkst.v.	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-25% Slenkst.v.	27	3	26	4	27	3	26	4	25	5	27	3	27	3	27	3
Slenkst.v.	15	15	14	16	15	15	14	16	15	15	16	14	16	14	15	15
+25% Slenkst.v.	4	26	3	27	4	26	3	27	4	26	3	27	4	26	3	27
+50% Slenkst.v.	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30
+300% Slenkst.v.	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30

Nark.medž.koncentracija Slenkstinės ribos	MDMA 1,000		MDMA 500		MOP 300		MOP 100		OPI		PCP		PPX		TCA	
	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
0% Slenkst.v.	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-50% Slenkst.v.	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-25% Slenkst.v.	26	4	25	5	27	3	26	4	27	3	25	5	26	4	25	5
Slenkst.v.	15	15	14	16	15	15	15	15	14	16	15	15	15	15	15	15
+25% Slenkst.v.	5	25	4	26	5	25	3	27	4	26	3	27	3	27	4	26
+50% Slenkst.v.	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30
+300% Slenkst.v.	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30

Nark.medž.koncentracija Slenkstinės ribos	TML 100		TML 200		TML 300		KET 1,000		KET 500		KET 300		KET 100		MQL	
	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
0% Slenkst.v.	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-50% Slenkst.v.	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-25% Slenkst.v.	27	3	27	3	27	3	27	3	27	3	26	4	27	3	26	4
Slenkst.v.	15	15	15	15	15	15	15	15	15	15	16	14	15	15	15	15
+25% Slenkst.v.	4	26	4	26	3	27	3	27	4	26	4	26	3	27	4	26
+50% Slenkst.v.	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30
+300% Slenkst.v.	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30

Nark.medž.koncentracija Slenkstinės ribos	OXY		COT 200		COT 100		EDDP 300		EDDP 100		FYL 20		FYL 10		K2 50	
	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
0% Slenkst.v.	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-50% Slenkst.v.	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-25% Slenkst.v.	27	3	27	3	27	3	27	3	26	4	27	3	27	3	27	3
Slenkst.v.	15	15	15	15	14	16	15	15	15	15	14	16	15	15	15	15
+25% Slenkst.v.	4	26	4	26	4	26	4	26	3	27	4	26	3	27	3	27
+50% Slenkst.v.	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30
+300% Slenkst.v.	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30

Nark.medž.koncentracija Slenkstinės ribos	K2 30		6-MAM 10		MDA 500		ETG500		ETG1000		CLO 400		CLO 150		LSD20	
	-	+	-	+	-	+	-	+	-	+	-	+	-	+		+
0% Slenkst.v.	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-50% Slenkst.v.	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-25% Slenkst.v.	27	3	27	3	26	4	26	4	26	4	26	4	26	4	27	3
Slenkst.v.	16	14	15	15	15	15	15	15	15	15	14	16	14	16	14	16
+25% Slenkst.v.	4	26	4	26	3	27	3	27	3	27	5	25	5	25	3	27
+50% Slenkst.v.	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30
+300% Slenkst.v.	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30

Nark.medž.koncentracija Slenkstinės ribos	LSD50		MPD		ZOL		MDMA 300		THC 200		MOP 200		MEP 100		MDPV 1000	
	-	+	-	+	-	+	-	-	+	+	-	+	-	+	-	+
0% Slenkst.v.	30	0	30	0	30	0	30	30	0	0	30	0	30	0	30	0
-50% Slenkst.v.	30	0	29	1	30	0	30	30	0	0	30	0	30	0	30	0
-25% Slenkst.v.	27	3	*	*	26	4	25	27	3	5	26	4	24	6	26	4
Slenkst.v.	14	16	15	15	14	16	15	17	13	15	15	15	17	13	14	16
+25% Slenkst.v.	3	27	*	*	5	25	3	5	25	27	4	26	4	26	3	27
+50% Slenkst.v.	0	30	1	29	0	30	0	0	30	30	0	30	0	30	0	30
+300% Slenkst.v.	0	30	0	30	0	30	0	0	30	30	0	30	0	30	0	30

Nark.medž.koncentracija Slenkstinės ribos	DIA 300		DIA 200		THC300		THC30		K2 25		ZOP 50		MCAT 500		MDPV 500	
	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
0% Slenkst.v.	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-50% Slenkst.v.	30	0	29	1	30	0	30	0	30	0	30	0	30	0	30	0
-25% Slenkst.v.	27	3	27	3	27	3	26	4	25	5	27	3	28	2	25	5
Slenkst.v.	15	15	15	15	14	16	14	16	14	16	17	13	17	13	15	15
+25% Slenkst.v.	3	27	3	27	4	26	4	26	3	27	4	26	3	27	3	27
+50% Slenkst.v.	0	30	1	29	0	30	0	30	0	30	0	30	0	30	0	30
+300% Slenkst.v.	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30

Nark.medž.koncentracija Slenkstinės ribos	7-ACL 300		7-ACL 200		7-ACL 100		CFYL 500		CAF 1000		CAT 150		TRO 350		ALP	
	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
0% Slenkst.v.	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-50% Slenkst.v.	30	0	30	0	29	1	30	0	30	0	30	0	30	0	30	0
-25% Slenkst.v.	26	4	27	3	27	3	25	5	27	3	27	3	27	3	28	2
Slenkst.v.	14	16	14	16	13	17	14	16	17	13	17	13	15	15	17	13
+25% Slenkst.v.	5	25	3	27	4	26	6	24	5	25	4	26	3	27	3	27
+50% Slenkst.v.	0	30	0	30	1	29	0	30	0	30	0	30	0	30	0	30
+300% Slenkst.v.	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30

Nark.medž.koncentracija Slenkstinės ribos	ABP 10	
	-	+
0% Slenkst.v.	30	0
-50% Slenkst.v.	30	0
-25% Slenkst.v.	25	5
Slenkst.v.	15	15
+25% Slenkst.v.	4	26
+50% Slenkst.v.	0	30
+300% Slenkst.v.	0	30

Analitinis specifiškumas

Žemiau esančioje lentelėje yra pateikiamos junginių koncentracijos (ng/mL), Multi-Drug greito testo panelio šlapime aptinkamos kaip teigiamos per 5 minutes.

Analitės	**Koncentrac. (ng/mL)**	**Analitės**	**Koncentrac. (ng/mL)**
ACETAMINOPHEN (ACE)			
Acetaminophen	5,000		
AMPHETAMINE (AMP 1,000)			
D,L-Amphetamine sulfate	300	Phentermine	1,000
L-Amphetamine	25,000	Maprotiline	50,000
(±) 3,4-Methylenedioxy amphetamine	500	Methoxyphenamine	6,000
		D-Amphetamine	1,000
AMPHETAMINE (AMP 500)			
D,L-Amphetamine sulfate	150	Phentermine	500
L-Amphetamine	12,500	Maprotiline	25,000
(±) 3,4-Methylenedioxy amphetamine	250	Methoxyphenamine	3,000
		D-Amphetamine	500
AMPHETAMINE (AMP 300)			
D,L-Amphetamine sulfate	75	Phentermine	300
L-Amphetamine	10,000	Maprotiline	15,000
(±) 3,4-Methylenedioxy amphetamine	150	Methoxyphenamine	2,000
		D-Amphetamine	300
BARBITURATES (BAR 300)			
Amobarbital	5,000	Alphenol	600
5,5-Diphenylhydantoin	8,000	Aprobarbital	500
Allobarbital	600	Butabarbital	200
Barbital	8,000	Butalbital	8,000
Talbutal	200	Butethal	500
Cyclopentobarbital	30,000	Phenobarbital	300
Pentobarbital	8,000	Secobarbital	300
BARBITURATES (BAR 200)			
Amobarbital	3,000	Alphenol	400
5,5-Diphenylhydantoin	5,000	Aprobarbital	300
Allobarbital	400	Butabarbital	150
Barbital	5,000	Butalbital	5,000
Talbutal	150	Butethal	300
Cyclopentobarbital	20,000	Phenobarbital	200
Pentobarbital	5,000	Secobarbital	200
BENZODIAZEPINES (BZO 500)			
Alprazolam	200	Bromazepam	1,500
a-hydroxyalprazolam	2,500	Chlordiazepoxide	1,500
Clobazam	300	Nitrazepam	300
Clonazepam	800	Norchlordiazepoxide	200
Clorazepatedipotassium	800	Nordiazepam	1,500
Delorazepam	1,500	Oxazepam	500
Desalkylflurazepam	300	Temazepam	300
Flunitrazepam	300	Diazepam	500
(±) Lorazepam	5,000	Estazolam	10,000
RS-Lorazepamglucuronide	300	Triazolam	5,000
Midazolam	10,000		
BENZODIAZEPINES (BZO 300)			
Alprazolam	100	Bromazepam	900
a-hydroxyalprazolam	1,500	Chlordiazepoxide	900
Clobazam	200	Nitrazepam	200
Clonazepam	500	Norchlordiazepoxide	100
Clorazepatedipotassium	500	Nordiazepam	900
Delorazepam	900	Oxazepam	300
Desalkylflurazepam	200	Temazepam	100
Flunitrazepam	200	Diazepam	300
(±) Lorazepam	3,000	Estazolam	6,000
RS-Lorazepamglucuronide	200	Triazolam	3,000
Midazolam	6,000		
BENZODIAZEPINES (BZO 200)			
Alprazolam	70	Bromazepam	600
a-hydroxyalprazolam	1,000	Chlordiazepoxide	600
Clobazam	120	Nitrazepam	120
Clonazepam	300	Norchlordiazepoxide	70
Clorazepatedipotassium	300	Nordiazepam	600
Delorazepam	600	Oxazepam	200
Desalkylflurazepam	120	Temazepam	70
Flunitrazepam	120	Diazepam	200
(±) Lorazepam	2,000	Estazolam	4,000
RS-Lorazepamglucuronide	120	Triazolam	2,000
Midazolam	4,000		
BENZODIAZEPINES (BZO 100)			
Alprazolam	40	Bromazepam	300
a-hydroxyalprazolam	500	Chlordiazepoxide	300
Clobazam	60	Nitrazepam	60
Clonazepam	150	Norchlordiazepoxide	40
Clorazepatedipotassium	150	Nordiazepam	300
Delorazepam	300	Oxazepam	100
Desalkylflurazepam	60	Temazepam	40
Flunitrazepam	60	Diazepam	100
(±) Lorazepam	1,000	Estazolam	2,000
RS-Lorazepamglucuronide	60	Triazolam	1,000
Midazolam	2,000		
BUPRENORPHINE (BUP 10)			
Buprenorphine	10	Norbuprenorphine	50
Buprenorphine 3-D-Glucuronide	50	Norbuprenorphine 3-D-Glucuronide	100
BUPRENORPHINE (BUP 5)			
Buprenorphine	5	Norbuprenorphine	25
Buprenorphine 3-D-Glucuronide	25	Norbuprenorphine 3-D-Glucuronide	50

COCAINE (COC 300)			
Benzoylecgonine	300	Cocaethylene	20,000
Cocaine HCl	200	Ecgonine	30,000
COCAINE (COC 200)			
Benzoylecgonine	200	Cocaethylene	13,500
Cocaine HCl	135	Ecgonine	20,000
COCAINE (COC 150)			
Benzoylecgonine	150	Cocaethylene	1,0000
Cocaine HCl	120	Ecgonine	15,000
COCAINE (COC 100)			
Benzoylecgonine	100	Cocaethylene	7,000
Cocaine HCl	80	Ecgonine	10,000
MARIJUANA (THC300)			
Cannabinol	200,000	△8-THC	100,000
11-nor-△8-THC-9 COOH	200	△9-THC	100,000
11-nor-△9-THC-9 COOH	300		
MARIJUANA (THC200)			
Cannabinol	140,000	△8-THC	68,000
11-nor-△8-THC-9 COOH	120	△9-THC	68,000
11-nor-△9-THC-9 COOH	200		
MARIJUANA (THC150)			
Cannabinol	100,000	△8-THC	50,000
11-nor-△8-THC-9 COOH	100	△9-THC	50,000
11-nor-△9-THC-9 COOH	150		
MARIJUANA (THC50)			
Cannabinol	35,000	△8-THC	17,000
11-nor-△8-THC-9 COOH	30	△9-THC	17,000
11-nor-△9-THC-9 COOH	50		
MARIJUANA (THC30)			
Cannabinol	20,000	△8-THC	10,000
11-nor-△8-THC-9 COOH	20	△9-THC	10,000
11-nor-△9-THC-9 COOH	30		
MARIJUANA (THC25)			
Cannabinol	17,500	△8-THC	8,500
11-nor-△8-THC-9 COOH	15	△9-THC	8,500
11-nor-△9-THC-9 COOH	25		
METHADONE (MTD300)			
Methadone	300	Doxylamine	100,000
METHADONE (MTD200)			
Methadone	200	Doxylamine	65,000
METHAMPHETAMINE (MET1, 000)			
ρ-Hydroxymethamphetamine	25,000	(±)-3,4-Methylenedioxy-methamphetamine	12,500
D-Methamphetamine	1,000		
L-Methamphetamine	20,000	Mephentermine	50,000
METHAMPHETAMINE (MET500)			
ρ-Hydroxymethamphetamine	12,500	(±)-3,4-Methylenedioxy-methamphetamine	6,250
D-Methamphetamine	500		
L-Methamphetamine	10,000	Mephentermine	25,000
METHAMPHETAMINE (MET300)			
ρ-Hydroxymethamphetamine	7,500	(±)-3,4-Methylenedioxy-methamphetamine	3,750
D-Methamphetamine	300		
L-Methamphetamine	6,000	Mephentermine	15,000
METHYLENEDIOXYMETHAMPHETAMINE (MDMA1, 000) Ecstasy			
(±) 3,4-Methylenedioxy methamphetamine HCl	1,000	3,4-Methylenedioxyethyl-amphetamine	600
(±)3,4-Methylenedioxy amphetamine HCl	6,000		
METHYLENEDIOXYMETHAMPHETAMINE (MDMA500) Ecstasy			
(±) 3,4-Methylenedioxy methamphetamine HCl	500	3,4-Methylenedioxyethyl-amphetamine	300
(±) 3,4-Methylenedioxy amphetamine HCl	3,000		
METHYLENEDIOXYMETHAMPHETAMINE (MDMA300) Ecstasy			
(±) 3,4-Methylenedioxy methamphetamine HCl	300	3,4-Methylenedioxyethyl-amphetamine	180
(±) 3,4-Methylenedioxy amphetamine HCl	1,800		
MORPHINE (MOP 300)			
Codeine	200	Norcodeine	6,000
Levorphanol	1,500	Normorphone	50,000
Morphine-3-β-D-Glucuronide	800	Oxycodone	30,000
Ethylmorphine	6,000	Oxymorphone	50,000
Hydrocodone	50,000	Procaine	15,000
Hydromorphone	3,000	Thebaine	6,000
6-Monoacethylmorphine	300	Morphine	300
MORPHINE (MOP 200)			
Codeine	160	Norcodeine	4,000
Levorphanol	1,000	Normorphone	40,000
Morphine-3-β-D-Glucuronide	600	Oxycodone	20,000
Ethylmorphine	4,000	Oxymorphone	40,000
Hydrocodone	40,000	Procaine	10,000
Hydromorphone	2,000	Thebaine	4,000
6-Monoacethylmorphine	200	Morphine	200
MORPHINE (MOP 100)			
Codeine	80	Norcodeine	2,000
Levorphanol	500	Normorphone	20,000
Morphine-3-β-D-Glucuronide	300	Oxycodone	10,000
Ethylmorphine	2,000	Oxymorphone	20,000
Hydrocodone	20,000	Procaine	5,000
Hydromorphone	1,000	Thebaine	2,000
6-Monoacethylmorphine	200	Morphine	100
Methaqualone (MQL 300)			
Methaqualone	300		
MORPHINE/OPIATE (OPI 2,000)			
Codeine	2,000	Morphine	2,000
Ethylmorphine	3,000	Norcodeine	25,000
Hydrocodone	50,000	Normorphone	50,000
Hydromorphone	15,000	Oxycodone	25,000
Levorphanol	25,000	Oxymorphone	25,000
6-Monoacetylmorphine	3,000	Procaine	50,000
Morphine 3-β-D-glucuronide	2,000	Thebaine	25,000
PHENCYCLIDINE (PCP)			
Phencyclidine	25	4-Hydroxyphencyclidine	12,500
PROPOXYPHENE (PPX)			
D-Propoxyphene	300	**D-Norpropoxyphene**	300
TRICYCLIC ANTIDEPRESSANTS (TCA)			
Nortriptyline	1,000	Imipramine	400
Nordoxepine	500	Clomipramine	50,000
Trimipramine	3,000	Doxepine	2,000
Amitriptyline	1,500	Maprotiline	2,000
Promazine	3,000	Promethazine	50,000
Desipramine	200	Perphenazine	50,000
Cyclobenzaprine	2,000	Dithiaden	10,000
TRAMADOL (TML 100)			
n-Desmethyl-cis-tramadol	200	o-Desmethyl-cis-tramadol	10,000
Cis-tramadol	100	Phencyclidine	100,000
Procyclidine	100,000	d,l-O-Desmethyl venlafaxine	50,000
TRAMADOL (TML 200)			
n-Desmethyl-cis-tramadol	400	o-Desmethyl-cis-tramadol	20,000
Cis-tramadol	200	Phencyclidine	200,000
Procyclidine	200,000	d,l-O-Desmethyl venlafaxine	100,000
TRAMADOL (TML 300)			
n-Desmethyl-cis-tramadol	600	o-Desmethyl-cis-tramadol	30,000
Cis-tramadol	300	Phencyclidine	300,000
Procyclidine	300,000	d,l-O-Desmethyl venlafaxine	150,000
KETAMINE (KET1, 000)			
Ketamine	1,000	Benzphetamine	25,000
Dextromethorphan	2,000	(+) Chlorpheniramine	25,000
Methoxyphenamine	25,000	Clonidine	100,000
d-Norpropoxyphene	25,000	EDDP	50,000
Promazine	25,000	4-Hydroxyphencyclidine	50,000
Promethazine	25,000	Levorphanol	50,000
Pentazocine	25,000	MDE	50,000
Phencyclidine	25,000	Meperidine	25,000
Tetrahydrozoline	500	d-Methamphetamine	50,000
Mephentermine	25,000	l-Methamphetamine	50,000
(1R, 2S) - (-)-Ephedrine	100,000	3,4-Methylendioxymethamphetamine (MDMA)	100,000
Disopyramide	25,000	Thioridazine	50,000
KETAMINE (KET500)			
Ketamine	500	Benzphetamine	12,500
Dextromethorphan	1,000	(+) Chlorpheniramine	12,500
Methoxyphenamine	12,500	Clonidine	50,000
d-Norpropoxyphene	12,500	EDDP	25,000
Promazine	12,500	4-Hydroxyphencyclidine	25,000
Promethazine	12,500	Levorphanol	25,000
Pentazocine	12,500	MDE	25,000
Phencyclidine	12,500	Meperidine	12,500
Tetrahydrozoline	250	d-Methamphetamine	25,000
Mephentermine	12,500	l-Methamphetamine	25,000
(1R, 2S) - (-)-Ephedrine	50,000	3,4-Methylendioxymethamphetamine (MDMA)	50,000
Disopyramide	12,500	Thioridazine	25,000
KETAMINE (KET300)			
Ketamine	300	Benzphetamine	6,250
Dextromethorphan	600	(+) Chlorpheniramine	6,250
Methoxyphenamine	6,250	Clonidine	30,000
d-Norpropoxyphene	6,250	EDDP	15,000
Promazine	6,250	4-Hydroxyphencyclidine	15,000
Promethazine	6,250	Levorphanol	15,000
Pentazocine	6,250	MDE	15,000
Phencyclidine	6,250	Meperidine	6,250
Tetrahydrozoline	150	d-Methamphetamine	15,000
Mephentermine	6,250	l-Methamphetamine	15,000
(1R, 2S) - (-)-Ephedrine	30,000	3,4-Methylendioxymethamphetamine (MDMA)	30,000
Disopyramide	6,250	Thioridazine	15,000
KETAMINE (KET100)			
Ketamine	100	Benzphetamine	2,000
Dextromethorphan	200	(+) Chlorpheniramine	2,000
Methoxyphenamine	2,000	Clonidine	10,000
d-Norpropoxyphene	2,000	EDDP	5,000
Promazine	2,000	4-Hydroxyphencyclidine	5,000
Promethazine	2,000	Levorphanol	5,000
Pentazocine	2,000	MDE	5,000
Phencyclidine	2,000	Meperidine	2,000
Tetrahydrozoline	50	d-Methamphetamine	5,000
Mephentermine	2,000	l-Methamphetamine	5,000
(1R, 2S) - (-)-Ephedrine	10,000	Thioridazine	5,000
Disopyramide	2,000	3,4-Methylendioxymethamphetamine (MDMA)	10,000
Oxycodone (OXY100)			
Oxycodone	100	Hydromorphone	50,000
Oxymorphone	300	Naloxone	25,000
Levorphanol	50,000	Naltrexone	25,000
Hydrocodone	25,000		
Cotinine (COT 200)			
(-)-Cotinine	200	(-)-Nicotine	5,000
Cotinine (COT 100)			
(-)-Cotinine	100	(-)-Nicotine	2,500
2-Ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP300)			
2-Ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP)			300
2-Ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP100)			
2-Ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP)			100
Fentanyl (FYL20)			
Alfentanyl	600,000	Buspirone	15,000
Fenfluramine	50,000	Fentanyl	100
Norfentanyl	20	Sufentanyl	50,000
Fentanyl (FYL10)			
Alfentanyl	300,000	Buspirone	8,000
Fenfluramine	25,000	Fentanyl	50
Norfentanyl	10	Sufentanyl	25,000
Synthetic Marijuana (K2-50)			
JWH-018 5-Pentanoic acid	50	JWH-073 4-butanoic acid	50
JWH-018 4-Hydroxypentyl	400	JWH-018 5-Hydroxypentyl	500
JWH-073 4-Hydroxybuty	500		
Synthetic Marijuana (K2-30)			
JWH-018 5-Pentanoic acid	30	JWH-073 4-butanoic acid	30
JWH-018 4-Hydroxypentyl	250	JWH-018 5-Hydroxypentyl	300
JWH-073 4-Hydroxybuty	300		
Synthetic Marijuana (K2-25)			
JWH-018 5-Pentanoic acid	25	JWH-073 4-butanoic acid	25
JWH-018 4-Hydroxypentyl	200	JWH-018 5-Hydroxypentyl	250
JWH-073 4-Hydroxybuty	250		
6-mono-aceto-morphine (6-MAM)			
6-Monoacethylmorphine	10	Morphine	100,000
(±) 3, 4-Methylenedioxyamphetamine (MDA 500)			
(±) 3,4-Methylenedioxy amphetamine	500	Methoxyphenamine D-Amphetamine	5,000 2,000
D,L-Amphetamine sulfate	400	Phentermine	2,000
L-Amphetamine	30,000	Maprotiline	100,000
Ethyl- β-D-Glucuronide(ETG500)			
Ethyl- β -D-Glucuronide	500	Propyl β-D-glucuronide	50,000
Morphine 3β-glucuronide	100,000	Morphine 6β-glucuronide	100,000
Glucuronic Acid	100,000	Ethanol	>100,000
Methanol	>100,000		
Ethyl- β-D-Glucuronide(ETG1,000)			
Ethyl- β -D-Glucuronide	1,000	Propyl β-D-glucuronide	100,000
Morphine 3β-glucuronide	>100,000	Morphine 6β-glucuronide	>100,000
Glucuronic Acid	>100,000	Ethanol	>100,000
Methanol	>100,000		
CLONAZEPAM(CLO 400)			
Clonazepam	400	Flunitrazepam	300
Alprazolam	200	(±) Lorazepam	1,250
a-hydroxyalprazolam	2,000	RS-Lorazepamglucuronide	250
Bromazepam	1,000	Midazolam	5,000
Chlordiazepoxide	1,000	Nitrazepam	200
Clobazam	250	Norchlordiazepoxide	200
Clorazepatedipotassium	600	Nordiazepam	1,000
Delorazepam	1,000	Oxazepam	350
Desalkylflurazepam	250	Temazepam	150
Diazepam	300	Triazolam	5,000
Estazolam	1,250		
CLONAZEPAM(CLO 150)			
Clonazepam	150	Flunitrazepam	120
Alprazolam	75	(±) Lorazepam	500
a-hydroxyalprazolam	750	RS-Lorazepamglucuronide	100
Bromazepam	400	Midazolam	2,000
Chlordiazepoxide	400	Nitrazepam	75
Clobazam	100	Norchlordiazepoxide	75
Clorazepatedipotassium	250	Nordiazepam	400
Delorazepam	400	Oxazepam	130
Desalkylflurazepam	100	Temazepam	60
Diazepam	120	Triazolam	2,000
Estazolam	500		
LYSERGIC ACID DIETHYLAMIDE (LSD 20)			
Lysergic Acid Diethylamide	20		
LYSERGIC ACID DIETHYLAMIDE (LSD 50)			
Promazine	2,000	4-Hydroxyphencyclidine	5,000
Promethazine	2,000	Levorphanol	5,000
Pentazocine	2,000	MDE	5,000
Phencyclidine	2,000	Meperidine	2,000
Tetrahydrozoline	50	d-Methamphetamine	5,000
Mephentermine	2,000	l-Methamphetamine	5,000
(1R, 2S) - (-)-Ephedrine	10,000	Thioridazine	5,000
Disopyramide	2,000	3,4-Methylendioxymethamphetamine (MDMA)	10,000

Lysergic Acid Diethylamide	50		
METHYLPHENIDATE (RITALIN)			
Methylphenidate (Ritalin)	300	Ritalinic Acid	1,000
ZOLPIDEM			
Zolpidem	50		
Mephedrone(MEP100)			
Mephedrone HCl	100	R(+)-Methcathinone HCl	1500
S(-)-Methcathinone HCl	500	3-Fluoromethcathinone HCl	1500
4-Fluoromethcathinone HCl	300	Methoxyphenamine	100,000
3, 4-methylenedioxypyrovalerone (MDPV1000)			
3, 4-methylenedioxypyrovalerone	1000		
3, 4-methylenedioxypyrovalerone (MDPV500)			
3, 4-methylenedioxypyrovalerone	500		
Diazepam (DIA 300)			
Diazepam	300	Midazolam	6,000
Clobazam	200	Nitrazepam	200
Clonazepam	500	Norchlordiazepoxide	100
Clorazepate dipotassium	500	Nordiazepam	900
Alprazolam	100	Flunitrazepam	200
a-hydroxyalprazolam	1,500	(±) Lorazepam	3,000
Bromazepam	900	RS-Lorazepam glucuronide	200
Chlordiazepoxide	900	Triazolam	3,000
Estazolam	6,000	Temazepam	100
Delorazepam	900	Oxazepam	300
Desalkylflurazepam	200		
Diazepam (DIA 200)			
Diazepam	200	Midazolam	4000
Clobazam	120	Nitrazepam	120
Clonazepam	300	Norchlordiazepoxide	70
Clorazepate dipotassium	300	Nordiazepam	600
Alprazolam	70	Flunitrazepam	120
a-hydroxyalprazolam	1000	(±) Lorazepam	2000
Bromazepam	600	RS-Lorazepam glucuronide	120
Chlordiazepoxide	600	Triazolam	2000
Estazolam	4000	Temazepam	70
Delorazepam	600	Oxazepam	200
Desalkylflurazepam	120		
Zopiclone (ZOP 50)			
Zopiclone-x-oxide	50	Zopiclone	50
Methcathinone (MCAT 500)			
S(-)-Methcathinone HCl	500	R(+)-Methcathinone HCl	1500
Methoxyphenamine	100000	3-Fluoromethcathinone HCl	1500
7-AMINOCLONAZEPAM(7-ACL300)			
a-hydroxyalprazolam	6,000	Flunitrazepam	3,000
Bromazepam	6,000	RS-Lorazepam glucuronide	2,700
Chlordiazepoxide	6,000	Norchlordiazepoxide	4,500
Clobazam	9,000	Nordiazepam	15,000
Clonazepam	2,400	Temazepam	9,000
Delorazepam	6,000	7-Aminoclonazepam	300
Desalkylflurazepam	6,000		
7-AMINOCLONAZEPAM(7-ACL200)			
a-hydroxyalprazolam	4,000	Flunitrazepam	2,000
Bromazepam	4,000	RS-Lorazepam glucuronide	1,800
Chlordiazepoxide	4,000	Norchlordiazepoxide	3,000
Clobazam	6,000	Nordiazepam	10,000
Clonazepam	1,600	Temazepam	6,000
Delorazepam	4,000	7-Aminoclonazepam	200
Desalkylflurazepam	4,000		
7-AMINOCLONAZEPAM(7-ACL100)			
a-hydroxyalprazolam	2,000	Flunitrazepam	1,000
Bromazepam	2,000	RS-Lorazepam glucuronide	900
Chlordiazepoxide	2,000	Norchlordiazepoxide	1,500
Clobazam	3,000	Nordiazepam	5,000
Clonazepam	800	Temazepam	3,000
Delorazepam	2,000	7-Aminoclonazepam	100
Desalkylflurazepam	2,000		
CARFENTANYL(CFYL500)			
Carfentanyl	500	Fentanyl	100
Caffeine (CAF 1000)			
Caffeine	1000		
Cathine (CAT 150)			
(+)-Norpseudoephedrine HCl (Cathine)	150	(+)3,4-Methylenedioxyamphetamine (MDA)	100
d/l-Amphetamine	100	p-Hydroxyamphetamine	100
Tryptamine	12,500	Methoxyphenamine	12,500
Tropicamide (TRO 350)			
Tropicamide	350		
Alprazolam(ALP 100)			
Benzodiazepines	300	Flunitrazepam	200
a-hydroxyalprazolam	1,500	(±) Lorazepam	3,000
Bromazepam	900	RS-Lorazepamglucuronide	200
Chlordiazepoxide	900	Midazolam	6,000
Clobazam	200	Nitrazepam	200
Clonazepam	500	Norchlordiazepoxide	100
Clorazepatedipotassium	500	Nordiazepam	900
Delorazepam	900	Oxazepam	300
Desalkylflurazepam	200	Temazepam	100

Diazepam	300	Triazolam	3,000
Estazolam	6000		
AB-PINACA (ABP 10)			
AB-PINACA	10	UR-144 4-hydroxypentyl	10,000
AB-PINACA 5-Pentanoic	10	APINACA 5-hydroxypentyl	10,000
AB-PINACA 5-hydroxypentyl	10	ADB-PINACA N-(5-hydroxypentyl)	30
AB-FUBINACA	10	ADB-PINACA Pentanoic Acid	10
AB-PINACA 4-hydroxypentyl	10,000	5-fluoro AB-PINACA N-(4-hydroxypentyl)	30
UR-144 5-Pentanoic	5,000	5-fluoro AB-PINACA	25
UR-144 5-hydroxypentyl	10,000		

Specifinio šlapimo tankio poveikis

Į penkiolika (15) šlapimo mėginių su normaliu, aukštu ir žemu specifiniu tankiu (1.005-1.045) buvo pridėta narkotinių medžiagų ties koncentracijomis 50% aukščiau ir 50% žemiau slenkstinių ribų. Multi-Drug greito testo panelis buvo tiriamas dvigubu pakartojimu, naudojant penkiolika mėginių be narkotinių medžiagų ir su pridėtomis narkotinėmis medžiagomis. Rezultatai parodė, jog skirtingas specifinio tankio spektras neįtakoja tyrimo rezultatų.

Šlapimo pH poveikis

Alikvotomis išpilstyto puluoto šlapimo pH buvo nustatytas ties 5 - 9 riba, 1 pH vieneto intervalais ir į jį buvo pridėta narkotinių medžiagų, ties koncentracijomis 50% virš ir 50% žemiau slenkstinių ribų. Šis šlapimas buvo tirtas su Multi-Drug greito testo paneliu. Rezultatai parodė, jog skirtingos pH ribos neinterferuoja tyrimo veiksmingumo.

Kryžminis reaktyvumas

Studijos metu buvo nustatomas kryžminis reaktyvumas tarp tyrimo ir junginių, esančių šlapime be narkotinių medžiagų ir su jomis, įskaitant amfetaminą, barbitūratus, benzodiazepinus, buprenorfiną, kokainą, marihuaną, metadoną, metamfetaminą, metilendioksimetamfetaminą, morfiną, tramadolį, ketaminą, fenciklidiną, propoksifeną bei triciklinius antidepresantus, oksikodoną, kotininą, EDDP, fentanilį, sintetinę marihuaną, 6-mono-aceto-morfiną, 3, 4-Metilendioksiamfetaminą, etil-β-D-Gliukuronidą, klonazepamą, lizerginės rūgšties dietilamidą, metilfenidatą ir zolpidemą. Žemiau pateikti junginiai neparodė jokio kryžminio reaktyvumo, kai buvo tiriami su Multi-Drug greito testo paneliu ties 100 µg/mL koncentracija.

Kryžmiškai nereaguojantys junginiai

Acetophenetidin	Cortisone	Zomepirac	d-Pseudoephedrine
N-Acetylprocainamide	Creatinine	Ketoprofen	Quinidine
Acetylsalicylic acid	Deoxycorticosterone	Labetalol	Quinine
Aminopyrine	Dextromethorphan	Loperamide	Salicylic acid
Amoxicillin	Diclofenac	Meprobamate	Serotonin
Ampicillin	Diflunisal	Isoxsuprine	Sulfamethazine
l-Ascorbic acid	Digoxin	d,l-Propanolol	Sulindac
Apomorphine	Diphenhydramine	Nalidixic acid	Tetracycline
Aspartame	Ethyl-p-aminobenzoate	Naproxen	Tetrahydrocortisone,
Atropine	β-Estradiol	Niacinamide	3-acetate
Benzilic acid	Estrone-3-sulfate	Nifedipine	Tetrahydrocortisone
Benzoic acid	Erythromycin	Norethindrone	Tetrahydrozoline
Bilirubin	Fenoprofen	Noscapine	Thiamine
d,l-Brompheniramine	Furosemide	d,l-Octopamine	Thioridazine
Caffeine	Gentisic acid	Oxalic acid	d,l-Tyrosine
Cannabidiol	Hemoglobin	Oxolinic acid	Tolbutamide
Chloral hydrate	Hydralazine	Oxymetazoline	Triamterene
Chloramphenicol	Hydrochlorothiazide	Papaverine	Trifluoperazine
Chlorothiazide	Hydrocortisone	Penicillin-G	Trimethoprim
d,l-Chlorpheniramine	o-Hydroxyhippuric acid	Perphenazine	d,l-Tryptophan
Chlorpromazine	3-Hydroxytyramine	Phenelzine	Uric acid
Cholesterol	d,l-Isoproterenol	Prednisone	Verapamil
Clonidine			

【ALKOHOLIO TESTO VEIKSMINGUMO CHARAKTERISTIKA】

Greito alkoholio šlapime testo aptikimo ribos yra nuo 0.02% iki 0.30% apytikslio santykinio alkoholio kiekio kraujyje. Slenkstinis tyrimo lygis gali skirtis priklausomai nuo vietinių taisyklių ir įstatymų. Tyrimo rezultatai gali būti lyginami su referentinėmis vertėmis, pateikiamomis spalvų lentelėje, esančioje ant folijos pakuotės.

【ALKOHOLIO TESTO SPECIFIŠKUMAS】

Greito alkoholio šlapime tyrimas reaguoja su metilo, etilo ir alilo alkoholiu.

【ALKOHOLIO TESTĄ INTERFERUOJANČIOS SUBSTANCIJOS】

Žemiau pateiktos substancijos gali interferuoti greitą alkoholio šlapime testą, jei bus naudojami ne šlapimo mėginiai. Pateiktų medžiagų paprastai nebūna tokio kiekio, kuris interferuotų tyrimą.

A. Agentai, kurie skatina spalvos kitimą
   - Peroksidazės
   - Stiprūs oksidatoriai

B. Agentai, kurie inhibuoja spalvos kitimą
   - Slopinantys agentai: askorbo rūgštis, tanino rūgštis, pirogalolis, merkaptanai ir tozilatai, oksalio rūgštis, šlapimo rūgštis
   - Bilirubinas
   - L-dopa
   - L-metildopa
   - Metampironas

【LITERATŪRA】

1. Hawks RL, CN Chiang. *Urine Testing for Drugs of Abuse*. National Institute for Drug Abuse (NIDA), Research Monograph 73, 1986.
2. Tietz NW. Textbook of Clinical Chemistry. W.B. Saunders Company. 1986; 1735.
3. Stewart DJ, Inaba T, Lucassen M, Kalow W. *Clin. Pharmacol. Ther.* April 1979; 25 ed: 464, 264-8.
4. Ambre J. *J. Anal. Toxicol.*1985; 9:241.
5. Winger, Gail, A Handbook of Drug and Alcohol Abuse, Third Edition, Oxford Press, 1992, page 146.
6. Robert DeCresce. *Drug Testing in the workplace,* 1989 page 114.
7. Glass, IB. The International Handbook of Addiction Behavior. Routledge Publishing, New York, NY. 1991; 216
8. B. Cody, J.T., "Specimen Adulteration in drug urinalysis. Forensic Sci. Rev., 1990, 2:63.
9. C. Tsai, S.C. et.al., J. Anal. Toxicol. 1998; 22 (6): 474
10. Baselt RC. Disposition of Toxic Drugs and Chemicals in Man. 6th Ed. Biomedical Publ., Foster City, CA 2002.
11. Hardman JG, Limbird LE. Goodman and Gilman's: The Pharmacological Basis for Therapeutics. 10th Edition. McGraw Hill Medical Publishing, 2001; 208-209.
12. Cumming, E. (22 April 2010). "Mephedrone: Chemistry lessons". London: The Daily Telegraph. Retrieved 2010-09-14.
13. "Drugs crackdown hailed a success". BBC News. 8 March 2010. Retrieved2010-03-31.
14. Kihara, Rhiannon; Day, Edward (May 2014). "Transient psychotic episodes following recreational use of NRG-3". Progress in Neurology and Psychiatry 18 (3): 14–18. doi:10.1002/pnp.331. Retrieved 22 March2015.
15. Schifano, F.; Albanese, A.; Fergus, S.; Stair, J. L.; Deluca, P.; Corazza, O.; Davey, Z.; Corkery, J.; Siemann, H.; Scherbaum, N.; Farre', M.; Torrens, M.; Demetrovics, Z.; Ghodse, A. H.; Psychonaut Web, M.; Rednet Research, G. (2010). "Mephedrone (4-methylmethcathinone; 'meow meow'): chemical, pharmacological and clinical issues".Psychopharmacology 214 (3):593–602. doi:10.1007/s00213-010-2070-x.ISSN 0033-3158. PMID 21072502.
16. "Assessment of Zopiclone" *(PDF).World Health Organization. Essential Medicines and Health Products World Health Organization. p.9 (Section 5. Pharmacokinetics)*. Retrieved5 December 2015.
17. Kratzsch C, Tenberken O, Peters FT et al. Screening, library-assisted identification, and validated quantification of 23 benzodiazepines, flumazenil, zaleplone, zolpidem, and zopiclone in plasma by liquid chromatography/mass spectrometry with atmospheric pressure chemical ionization. J. Mass Spec. 39: 856-872, 2004.
18. Gustavsen I, Al-Sammurraie M, Mørland J, Bramness JG. Impairment related to blood drug concentrations of zopiclone and zolpidem compared with alcohol in apprehended drivers. Accid. Anal. Prev. 41: 462-466, 2009.
19. R. Baselt, Disposition of Toxic Drugs and Chemicals i Man, 8th edition, Biomedical Publications, Foster City, CA, 2008, pp. 1677-1679.
20. Calkins RF, Aktan GB, Hussain KL (1995). "Methcathinone: the next illicit stimulant epidemic?". Journal of Psychoactive Drugs. 27 (3): 277–85. doi:10.1080/02791072.1995.10472472. PMID 8594170.
21. Methcathinone, https://en.wikipedia.org/wiki/Methcathinone.
22. Bersani, F. S.; Corazza, O.; Simonato, P.; Mylokosta, A.; Levari, E.; Lovaste, R.; Schifano, F. (2013). "Drops of madness? Recreational misuse of tropicamide collyrium; early warning alerts from Russia and Italy".General Hospital Psychiatry 35 (5):571–3.Baselt RC. Disposition of Toxic Drugs and Chemicals in Man. 2nd Ed. Biomedical Publ., Davis, CA. 1982; 488
23. Malenka RC, Nestler EJ, Hyman SE (2009). "Chapter 15: Reinforcement and Addictive Disorders". In Sydor A, Brown RY. Molecular Neuropharmacology: A Foundation for Clinical Neuroscience (2nd ed.).NewYork:McGraw-Hill Medical. p. 375. ISBN 9780071481274.
24. American Psychiatric Association (2013). "Substance-Related and Addictive Disorders". American Psychiatric Publishing. pp. 1–2. Retrieved 10 July 2015.
25. Juliano LM, Griffiths RR (2004). "A critical review of caffeine withdrawal: empirical validation of symptoms and signs, incidence, severity, and associated features". Psychopharmacology (Berl.) 176 (1):1–29. doi:10.1007/s00213-004-2000-x. PMID 15448977. Archived from the original on 29 January 2012.
26. Arnaud MJ. Pharmacokinetics and metabolism of natural methylxanthines in animal and man. Handb Exp Pharmacol 2011; 200:33-91.
27. Jeukendrup AE, Randell R-Fat burners: nutrition supplements that increase fat metabolism. Obes Rev 2011; 193:1-24.
28. Cumming, E. (22 April 2010). "Mephedrone: Chemistry lessons". London: The Daily Telegraph. Retrieved 2010-09-14.
29. "Drugs crackdown hailed a success". BBC News. 8 March 2010. Retrieved2010-03-31.
30. Kihara, Rhiannon; Day, Edward (May 2014). "Transient psychotic episodes following recreational use of NRG-3". Progress in Neurology and Psychiatry 18 (3): 14–18. doi:10.1002/pnp.331. Retrieved 22 March2015.
31. Schifano, F.; Albanese, A.; Fergus, S.; Stair, J. L.; Deluca, P.; Corazza, O.; Davey, Z.; Corkery, J.; Siemann, H.; Scherbaum, N.; Farre', M.; Torrens, M.; Demetrovics, Z.; Ghodse, A. H.; Psychonaut Web, M.; Rednet Research, G. (2010). "Mephedrone (4-methylmethcathinone; 'meow meow'): chemical, pharmacological and clinical issues".Psychopharmacology 214 (3):593–602. doi:10.1007/s00213-010-2070-x.ISSN 0033-3158. PMID 21072502.
32. Work Group on Panic Disorder (January 2009). APA Practice Guideline for the Treatment of Patients With Panic Disorder (2nd ed.).
33. "FDA approved labeling for Xanax revision 08/23/2011" (PDF).Federal Drug Administration. 2011-08-23. p. 4. Retrieved 2011-09-14.
    "Xanax XR (Alprazolam) Clinical Pharmacology – Prescription Drugs and Medications". RxList. First DataBank. July 2008.
34. "AB-PINACA". Cayman Chemical. Retrieved 25 June 2015.
35. Banister, Samuel D.; Moir, Michael; Stuart, Jordyn; Kevin, Richard C.; Wood, Katie E.; Longworth, Mitchell; Wilkinson, Shane M.; Beinat, Corinne; Buchanan, Alexandra S.; Glass, Michelle; Connor, Mark; McGregor, Iain S.; Kassiou, Michael (2015). "Pharmacology of Indole and Indazole Synthetic Cannabinoid Designer Drugs AB-FUBINACA, ADB-FUBINACA, AB-PINACA, ADB-PINACA, 5F-AB-PINACA, 5F-ADB-PINACA, ADBICA, and 5F-ADBICA". ACS Chemical Neuroscience. 6 (9): 1546–59.
36. Jenny L Wiley; Julie A Marusich; Timothy W Lefever; Kateland R Antonazzo; Michael T Wallgren; Ricardo A Cortes; Purvi R Patel; Megan Grabenauer; Katherine N Moore; Brian F Thomas (June 2015). "AB-CHMINACA, AB-PINACA, and FUBIMINA: Affinity and Potency of Novel Synthetic Cannabinoids in Producing Δ9-Tetrahydrocannabinol-Like Effects in Mice". Journal of Pharmacology and Experimental Therapeutics. 354 (3): 328–39. PMC 4538877 Freely accessible.

Simbolių rodyklė

	Dėmesio, skaitykite naudojimo instrukcijas		Tyrimų rinkinyje	EC REP	Įgaliotas atstovas
IVD	Tik in vitro diagnostiniam naudojimui		Naudoti iki		Nenaudoti pakartotinai
2°C 30°C	Laikyti prie 2-30°C	LOT	Partijos numeris	REF	Katalogo nr.
	Nenaudokite, jei pakuotė pažeista		Gamintojas		Naudojimo instrukcijos

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CE

Tikslus dokumento vertimas į lietuvių kalbą

Vertėja Akvilė Gegelevičienė

Data 2018-11-05

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