COCII

ONLINE DAT Cocaine II

cobas®

Drug abuse testing

Order information

REF	CONTENT		Analyzers on which **cobas c** pack can be used
03800130 190	ONLINE DAT Cocaine II (200 tests)	System-ID 07 6723 9	COBAS INTEGRA 400 plus COBAS INTEGRA 800
03304671 190	Preciset DAT Plus I CAL 1-6 (6 × 5 mL)		
03304698 190	C.f.a.s. DAT Qualitative Plus (6 × 5 mL)		
04590856 190	C.f.a.s. DAT Qualitative Plus Clinical (3 × 5 mL)		
03312950 190	Control Set DAT I (for 150 ng/mL assay) PreciPos DAT Set I (2 × 10 mL) PreciNeg DAT Set I (2 × 10 mL)		
03312976 190	Control Set DAT III (for 300 ng/mL assay) PreciPos DAT Set III (2 × 10 mL) PreciNeg DAT Set III (2 × 10 mL)		
04500873 190	Control Set DAT Clinical (for 300 ng/mL assay) PreciPos DAT Clinical (2 × 10 mL) PreciNeg DAT Clinical (2 × 10 mL)		

English

System information

Test CO1S2, test-ID 0-126 for semiquantitative assay, 150 ng/mL

Test CO3S2, test-ID 0-127 for semiquantitative assay, 300 ng/mL

Test CO1Q2, test-ID 0-015 for qualitative assay, 150 ng/mL

Test CO3Q2, test-ID 0-016 for qualitative assay, 300 ng/mL

Test CO3QC, test-ID 0-115 for qualitative assay, 300 ng/mL; using C.f.a.s. DAT Qualitative Plus Clinical

Intended use

Cocaine II (COCII) is an in vitro diagnostic test intended for the semiquantitative and qualitative detection of benzoylecgonine, the primary metabolite of cocaine, in human urine at cutoff concentrations of 150 ng/mL and 300 ng/mL on COBAS INTEGRA systems. Semiquantitative test results may be obtained that permit laboratories to assess assay performance as part of a quality control program. Semiquantitative assays are intended to determine an appropriate dilution of the specimen for confirmation by a confirmatory method such as gas chromatography/mass spectrometry (GC/MS).

Cocaine II provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. GC/MS is the preferred confirmatory method.[1] Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

Summary

Cocaine, a natural product found in the leaves of the coca plant, is a potent central nervous system (CNS) stimulant and a local anesthetic. Its pharmacological effects are identical to those of amphetamines (also CNS stimulants), though cocaine has a shorter duration of action.[2] Cocaine induces euphoria, confidence, and a sense of increased energy in the user; these psychological effects are accompanied by increased heart rate, dilation of pupils, fever, tremors, and sweating. The “crash” following a cocaine high is profound, ranging from irritability, lassitude, and the desire for more drug, to anxiety, hallucinations, and paranoia.[3,4] Users may revert to other drugs at this time to relieve the depressive effects of the “crash”.[2]

Cocaine is traditionally administered intranasally or smoked in its purer, free-base form; oral ingestion is ineffective, as cocaine is broken down in the gastrointestinal tract. It is absorbed readily across the mucous membranes of the nose and lungs into the circulation. Its effects are intense but short-lived. Cocaine is rapidly inactivated by hydrolysis of its ester linkages.[1,5,6] Blood cholinesterases hydrolyze cocaine to ecgonine methyl ester, while hydrolysis of the parent drug to benzoylecgonine is thought to be non-enzymatic; both of these metabolites may be further hydrolyzed to ecgonine. Unmetabolized cocaine has an affinity for fatty tissue and rapidly enters the brain; cocaine metabolites, however, are more water soluble and are readily excreted in the urine along with some portion of unchanged drug.[5,7] The prominent benzoylecgonine metabolite is the primary urinary marker for detecting cocaine use.[1,5]

Tolerance has been observed with some chronic, high-dose users.[8] Physical dependence does not appear to occur in abusers, although the development of strong psychological dependence is well known. Cessation of drug use may result in depression, hallucinations, and in extreme cases, psychosis.[2]

Test principle

Kinetic interaction of microparticles in a solution (KIMS)[9,10] as measured by changes in light transmissions.

In the absence of sample drug, soluble drug conjugates bind to antibody-bound microparticles, causing the formation of particle aggregates. As the aggregation reaction proceeds in the absence of sample drug, the absorbance increases.

When a urine sample contains the drug in question, this drug competes with the drug derivative conjugate for microparticle-bound antibody. Antibody bound to sample drug is no longer available to promote particle aggregation, and subsequent particle lattice formation is inhibited. The presence of sample drug diminishes the increasing absorbance in proportion to the concentration of drug in the sample. Sample drug content is determined relative to the value obtained for a known cutoff concentration of drug.[11]

Reagents - working solutions

R1 Conjugate Reagent

Conjugated benzoylecgonine derivative in buffer with BSA and 0.09 % sodium azide.

SR Antibody/Microparticle Reagent

Microparticles attached to benzoylecgonine antibody (mouse monoclonal) in buffer with BSA and 0.09 % sodium azide.

R1 is in position B and SR is in position C.

Precautions and warnings

Pay attention to all precautions and warnings listed in Section 1 / Introduction of this Method Manual.

For USA: For prescription use only.

Reagent handling

COBAS INTEGRA 400 plus analyzer

Mix all new (non-punctured) **cobas c** packs for 1 minute on a cassette mixer before loading on the analyzer. All in-use **cobas c** packs must also be mixed in the same manner at the beginning of each week (once a week).

COBAS INTEGRA 800 analyzer

Ready for use. After **cobas c** pack puncture, the analyzer automatically mixes the reagent for 1 minute and for half a minute during Begin of Day.

Storage and stability

Shelf life at 2-8 °C:	See expiration date on **cobas c** pack label

| COBAS INTEGRA 400 plus analyzer

On-board in use at 10-15 °C 12 weeks

COBAS INTEGRA 800 analyzer

On-board in use at 8 °C 12 weeks

| Do not freeze reagents. Reagents that have been frozen should be discarded.

Specimen collection and preparation

Only the specimens listed below were tested and found acceptable.

Urine: Collect urine samples in clean glass or plastic containers. Fresh urine specimens do not require any special handling or pretreatment, but an effort should be made to keep pipetted samples free of gross debris. Samples should be within the normal physiological pH range of 5-8. No additives or preservatives are required. It is recommended that urine specimens be stored at 2-8 °C and tested within 5 days of collection.[12]

For prolonged storage, freezing of the sample is recommended.

Centrifuge highly turbid specimens before testing.

Adulteration or dilution of the sample can cause erroneous results. If adulteration is suspected, another sample should be collected. Specimen validity testing is required for specimens collected under the *Mandatory Guidelines for Federal Workplace Drug Testing Programs*.[13]

Caution: Specimen dilutions should only be used as an estimation for GC/MS and are not intended for patient values. Dilution procedures, when used, should be validated.

Materials provided

See "Reagents – working solutions" section for reagents.

Assay

For optimum performance of the assay follow the directions given in this document for the analyzer concerned. Refer to the appropriate operator's manual for analyzer-specific assay instructions.

Application for urine

| **COBAS INTEGRA 400 plus test definition**

	150 and 300 ng/mL cutoffs	
	Semiquantitative	*Qualitative*
Measuring mode	Absorbance	Absorbance
Abs. calculation mode	Endpoint	Endpoint
Reaction mode	R1-S-SR	R1-S-SR
Reaction direction	Increase	Increase
Reaction start	SR	SR
Wavelength A	629 nm	629 nm
Test range	0-5000 ng/mL	0-9000 *CO1Q2* 0-4000 *CO3Q2 CO3QC*
with postdilution	0-50000 ng/mL	
Postdilution factor	10 recommended[a)]	No
Calc. first/last	35/46	35/46
Unit	ng/mL	

a) For use when estimating concentration in preparation for GC/MS analysis.

Pipetting parameters

		Diluent (H_2O)
R1	90 µL	5 µL
Sample	8 µL	3 µL
SR	35 µL	3 µL
Total volume	144 µL	

COBAS INTEGRA 800 test definition

	150 and 300 ng/mL cutoffs	
	Semiquantitative	*Qualitative*
Measuring mode	Absorbance	Absorbance
Abs. calculation mode	Endpoint	Endpoint
Reaction mode	R1-S-SR	R1-S-SR
Reaction direction	Increase	Increase
Reaction start	SR	SR
Wavelength A	629 nm	629 nm
Test range	0-5000 ng/mL	0-9000 *CO1Q2* 0-4000 *CO3Q2 CO3QC*
with postdilution	0-50000 ng/mL	
Postdilution factor	10 recommended[b)]	No
Calc. first/last	45/78	45/78
Unit	ng/mL	

b) For use when estimating concentration in preparation for GC/MS analysis.

Pipetting parameters

		Diluent (H_2O)
R1	90 µL	5 µL
Sample	8 µL	3 µL
SR	35 µL	3 µL
Total volume	144 µL	

Calibration

Calibrators		*Semiquantitative applications*
	CO1S2, 0-126 *CO3S2, 0-127*	Preciset DAT Plus I calibrators, CAL1-6 0, 75, 150, 300, 1000, 5000 ng/mL benzoylecgonine (DATS2, system-ID 07 6764 6)
		Qualitative applications
	CO1Q2, 0-015	Preciset DAT Plus I calibrators, CAL 1 0 ng/mL *or* deionized water *and* Preciset DAT Plus I calibrators, CAL 3[c)] *or* C.f.a.s. DAT Qualitative Plus 150 ng/mL (150 cutoff, DATQ1, system-ID 07 6744 1)
		For qualitative applications, the cutoff of 150 ng/mL is assigned a value of 1000.
	CO3Q2, 0-016	Preciset DAT Plus I calibrators, CAL 1 0 ng/mL *or* deionized water *and* Preciset DAT Plus I calibrators, CAL 4 300 ng/mL (300 cutoff, DATQ2, system-ID 07 6768 9)

CO3QC, 0-115	Preciset DAT Plus I or II[d] calibrators, CAL 1 0 ng/mL *or* deionized water *and* C.f.a.s. DAT Qualitative Plus Clinical 300 ng/mL (300 cutoff, DATQ5, system-ID 07 6880 4) For qualitative applications, the cutoff of 300 ng/mL is assigned a value of 1000.

c) Do not use Preciset DAT Plus I, CAL 3 if calibrating the Opiates 300/2000 qualitative 2000 ng/mL assay (test OP2QL, test-ID 0-410).

d) Preciset DAT Plus II, CAL 1, while generally not required for the calibration of Cocaine II, may be used as an alternative 0 ng/mL level for DATQ5, system-ID 07 6880 4.

Calibration mode	*Semiquantitative applications* Logit/Log 4 *Qualitative applications* Linear regression
Calibration replicate	Duplicate recommended
Calibration interval	COBAS INTEGRA 400 plus analyzer: Each lot, every 4 weeks, and as required following quality control procedures COBAS INTEGRA 800 analyzer: Each lot, every 4 weeks, and as required following quality control procedures

A calibration curve is generated using the calibrators. Calibrators must be placed from the highest concentration first to the lowest last on the CAL/QC rack. This curve is retained in memory by the COBAS INTEGRA system and recalled for later use.

Traceability: This method has been standardized against a primary reference method (GC/MS).

Quality control

Quality control	*150 ng/mL cutoff* Control Set DAT I PreciPos DAT Set I (DAT1P, system-ID 07 6753 0) PreciNeg DAT Set I (DAT1N, system-ID 07 6754 9) *300 ng/mL cutoff* Control Set DAT III PreciPos DAT Set III (DAT3P, system-ID 07 6773 5) PreciNeg DAT Set III (DAT3N, system-ID 07 6774 3) *or* Control Set DAT Clinical PreciPos DAT Clinical (DATCP, system-ID 07 6879 0) PreciNeg DAT Clinical (DATCN, system-ID 07 6878 2)
Control sequence	User defined
Control after calibration	Recommended

For quality control, use control materials as listed in the “Order information” section. In addition, other suitable control material can be used.

Drug concentrations of Control Set DAT I, III, and Clinical have been verified by GC/MS.

The control intervals and limits should be adapted to each laboratory’s individual requirements. Values obtained should fall within the defined limits. Each laboratory should establish corrective measures to be taken if values fall outside the defined limits.

Follow the applicable government regulations and local guidelines for quality control.

Results

COBAS INTEGRA systems report results with the following test flags:

Semiquantitative result reporting
CO1S2 (150 ng/mL cutoff)

Flag	COBAS INTEGRA	Value range
No flag	Negative	< 150 ng/mL
<TEST RNG	Negative	< 0 ng/mL
>TEST RNG	Positive	> 5000 ng/mL
POS 150	Positive	≥ 150 ng/mL

Value ranges listed above are based on a cutoff value of 150 ng/mL.

CO3S2 (300 ng/mL cutoff)

Flag	COBAS INTEGRA	Value range
No flag	Negative	< 300 ng/mL
<TEST RNG	Negative	< 0 ng/mL
>TEST RNG	Positive	> 5000 ng/mL
POS 300	Positive	≥ 300 ng/mL

Value ranges listed above are based on a cutoff value of 300 ng/mL.

Qualitative result reporting
CO1Q2 (150 ng/mL cutoff)

Flag	COBAS INTEGRA	Value range
No flag	Negative	< 1000
<TEST RNG	Negative	< 0
>TEST RNG	Positive	> 9000
POS 1000	Positive	≥ 1000

Value ranges above are based on assigning the cutoff of 150 ng/mL a value of 1000.

CO3Q2, CO3QC (300 ng/mL cutoff)

Flag	COBAS INTEGRA	Value range
No flag	Negative	< 1000
<TEST RNG	Negative	< 0
>TEST RNG	Positive	> 4000
POS 1000	Positive	≥ 1000

Value ranges above are based on assigning the cutoff of 300 ng/mL a value of 1000.

Semiquantitative result reporting

The semiquantitation of preliminary positive results should only be used by laboratories to determine an appropriate dilution of the specimen for confirmation by a confirmatory method such as GC/MS. It also permits the laboratory to establish quality control procedures and assess control performance.

Note: When using the post-dilution function (1:10 dilution), to ensure the sample was not over-diluted, the diluted result must be at least half the analyte cutoff value times 10. If the diluted result falls below half the analyte cutoff value times 10, repeat the sample with a smaller dilution. A dilution that produces a result closest to the analyte cutoff is the most accurate estimation. To estimate the preliminary positive sample’s concentration, multiply the result by the appropriate dilution factor. Dilutions should only be used as an estimation for GC/MS.

Limitations - interference

See the “Specific performance data” section of this document for information on substances tested with this assay. There is the possibility

that other substances and/or factors may interfere with the test and cause erroneous results (e.g., technical or procedural errors).

A preliminary positive result with this assay indicates the presence of cocaine metabolite in urine. It does not measure the level of intoxication.

For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.

Interfering substances were added to drug free urine at twice the concentration listed below. These samples were then spiked to 150 ng/mL using a 300 ng/mL benzoylecgonine stock solution. Samples were tested and the following results were obtained:

Substance	Concentration tested	% Cocaine Metabolite Recovery
Acetone	1 %	96
Ascorbic Acid	1.5 %	113
Bilirubin	0.25 mg/mL	106
Creatinine	5 mg/mL	107
Ethanol	1 %	96
Glucose	2 %	109
Hemoglobin	0.1 g/L	101
Hemoglobin	1 g/L	99
Hemoglobin	7.5 g/L	106
Human Albumin	0.025 %	104
Human Albumin	0.05 %	107
Human Albumin	0.5 %	104
Oxalic Acid	2 mg/mL	106
Sodium Chloride	0.5 M	94
Sodium Chloride	1 M	91
Urea	6 %	110

Interfering substances were added to drug free urine at twice the concentration listed below. These samples were then spiked to 300 ng/mL using a 600 ng/mL benzoylecgonine stock solution. Samples were tested and the following results were obtained:

Substance	Concentration tested	% Cocaine Metabolite Recovery
Acetone	1 %	99
Ascorbic Acid	1.5 %	112
Bilirubin	0.25 mg/mL	102
Creatinine	5 mg/mL	104
Ethanol	1 %	99
Glucose	2 %	104
Hemoglobin	0.1 g/L	104
Hemoglobin	1 g/L	104
Hemoglobin	7.5 g/L	104
Human Albumin	0.025 %	105
Human Albumin	0.05 %	103
Human Albumin	0.5 %	106
Oxalic Acid	2 mg/mL	102
Sodium Chloride	0.5 M	96
Sodium Chloride	1 M	95
Urea	6 %	101

ACTION REQUIRED

Special Wash Programming: The use of special wash steps is mandatory when certain test combinations are run together on COBAS INTEGRA analyzers. Refer to the CLEAN Method Sheet for further instructions and for the latest version of the Extra wash cycle list.

Where required, special wash/carry-over evasion programming must be implemented prior to reporting results with this test.

Specific performance data

Representative performance data on the COBAS INTEGRA analyzers are given below. Results obtained in individual laboratories may differ.

Precision

Precision was determined in an internal protocol by using a series of benzoylecgonine calibrator and controls in replicates of 20, once a day, for 5 days.

The following results were obtained on a COBAS INTEGRA 700 analyzer:

Semiquantitative precision (150 ng/mL cutoff)

Repeatability	Mean ng/mL	SD ng/mL	CV %
Level 1 (113 ng/mL)	118	5	4.4
Level 2 (150 ng/mL)	161	6	3.8
Level 3 (188 ng/mL)	184	5	2.8

Intermediate precision	Mean ng/mL	SD ng/mL	CV %
Level 1 (113 ng/mL)	119	6	5.3
Level 2 (150 ng/mL)	155	7	4.5
Level 3 (188 ng/mL)	188	7	3.7

Semiquantitative precision (300 ng/mL cutoff)

Repeatability	Mean ng/mL	SD ng/mL	CV %
Level 1 (225 ng/mL)	199	5	2.7
Level 2 (300 ng/mL)	296	7	2.3
Level 3 (375 ng/mL)	355	7	2.0

Intermediate precision	Mean ng/mL	SD ng/mL	CV %
Level 1 (225 ng/mL)	208	8	3.9
Level 2 (300 ng/mL)	294	10	3.4
Level 3 (375 ng/mL)	341	12	3.5

Qualitative precision

150 ng/mL cutoff; 300 ng/mL cutoff

Cutoff (x)	Number tested	Correct results	Confidence level
0.75x	100	100	> 95 % negative reading
1.25x	100	100	> 95 % positive reading

Lower detection limit of the test

7 ng/mL (150 ng/mL and 300 ng/mL cutoff assays)

The lower detection limit represents the lowest measurable analyte level that can be distinguished from zero. It is calculated as the value lying 2 standard deviations above that of the zero calibrator (zero calibrator + 2 SD, repeatability, n = 21).

Accuracy

100 urine samples, obtained from a clinical laboratory where they screened negative in a drug test panel by another technology, were evaluated for cocaine metabolite on a COBAS INTEGRA 700 analyzer. All 100 clinical samples were negative relative to the 150 ng/mL and 300 ng/mL cutoffs.

50 urine samples, obtained from clinical laboratories where they screened preliminary positive by a commercially available enzyme immunoassay and confirmed positive for cocaine metabolite by GC/MS, were also evaluated on a COBAS INTEGRA 700 analyzer. All 50 samples were positive with the COBAS INTEGRA Cocaine II assay relative to the 150 ng/mL and 300 ng/mL cutoffs.

In addition, 10 samples were diluted to a benzoylecgonine concentration of 75-100 % of the cutoff concentration for each cutoff; and 10 samples were diluted to a benzoylecgonine concentration of 100-125 % of the cutoff concentration for each cutoff.

Data from the accuracy studies described above that fell within the near cutoff value ranges were combined with data generated from the diluted positive urine samples. The following results were obtained with Cocaine II on a COBAS INTEGRA 700 analyzer relative to the GC/MS values.

Cocaine II Clinical Correlation (Cutoff = 150 ng/mL)

COBAS INTEGRA 700 analyzer		Negative samples	GC/MS values (ng/mL)		
			Near cutoff		
			113	188	344-106072
	+	0	0	10	50
	–	100	10	0	0

Cocaine II Clinical Correlation (Cutoff = 300 ng/mL)

COBAS INTEGRA 700 analyzer		Negative samples	GC/MS values (ng/mL)		
			Near cutoff		
			225	309-402	428-106072
	+	0	0	11	49
	–	100	10	0	0

Analytical specificity

The specificity of the COBAS INTEGRA Cocaine II assay for cocaine and its metabolites was determined by generating inhibition curves for each of the compounds listed and determining the approximate quantity of each compound that is equivalent in assay reactivity to the 150 ng/mL and 300 ng/mL benzoylecgonine assay cutoffs.

Compound	Approximate ng/mL equivalent to 150 ng/mL of benzoylecgonine	Approximate percent cross-reactivity
Cocaine	7112	2.1
Cocaethylene	37260	0.4

Compound	Approximate ng/mL equivalent to 300 ng/mL of benzoylecgonine	Approximate percent cross-reactivity
Cocaine	18508	1.6
Cocaethylene	70108	0.4

Additionally, the following compounds were tested at a concentration of 100000 ng/mL in pooled human urine and shown to have cross-reactivity values of less than 0.05 %:

Ecgonine	Ecgonine methyl ester	Norcocaine

Drug interference

The following compounds were added to aliquots of pooled normal human urine at a concentration of 100000 ng/mL. None of these compounds gave values in the assay that were equal to or greater than 0.05 % (50 ng/mL) cross reactivity.

Acetaminophen	EDDP	Nordoxepin
Acetylsalicylic acid	EMDP	Norethindrone
Aminopyrine	Erythromycin	*l*-Norpseudoephedrine
Amitriptyline	Estriol	Nortriptyline
Amobarbital	Fenoprofen	Orphenadrine
d-Amphetamine	Fluconazole	Oxazepam
l-Amphetamine	Fluoxetine	Oxycodone
Ampicillin	Furosemide	Penicillin G
Ascorbic acid	Gentisic acid	Pentobarbital
Aspartame	Glutethimide	Perphenazine
Atropine	Guaiacol glycerol ether	β-Phenethylamine
Benzocaine	Haloperidol	Phencyclidine
Benzphetamine	Hydrochlorothiazide	Phenobarbital
Butabarbital	Hydroxymethadone	Phenothiazine
Caffeine	Ibuprofen	Phentermine
Calcium hypochlorite	Imipramine	Phenylbutazone
Cannabidiol	Isoproterenol	Phenylpropanolamine
Carbamazepine	Ketamine	*d*-Phenylpropanolamine
Chlordiazepoxide	LAAM	Phendimetrazine
Chloroquine	Lidocaine	Procaine
Chlorpheniramine	LSD	Promazine
Chlorpromazine	Maprotiline	Promethazine
Chlorprothixene	MDA	Propoxyphene
Clomipramine	MDMA	Protriptyline
Codeine	Melanin	*d*-Pseudoephedrine
Cotinine	Meperidine	*l*-Pseudoephedrine
Cyclobenzaprine	Methadol	Quinidine
Cyproheptadine	Methadone	Quinine
Desipramine	*d*-Methamphetamine	Secobarbital
Dextromethorphan	*l*-Methamphetamine	Sulindac
Dextropropoxyphene	Methaqualone	Tetracycline
Diazepam	Methotrimeprazine	Δ^9THC-9-carboxylic acid
Diphenhydramine	Methylphenidate	Tetrahydrozoline
Diphenylhydantoin	Methyprylon	Thioridazine
Dopamine	Mianserin	Thiothixene
Disopyramide	Morphine sulfate	Trifluoperazine
Doxepin	Naloxone	Trimipramine
Doxylamine	Naltrexone	Tyramine
d-Ephedrine	Naproxen	Verapamil
d,l-Ephedrine	Niacinamide	Zomepirac
l-Ephedrine	Nicotine	
Epinephrine	Nordiazepam	

Any modification of the instrument as set forth in this labeling requires validation by the laboratory.

References

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A point (period/stop) is always used in this Method Sheet as the decimal separator to mark the border between the integral and the fractional parts of a decimal numeral. Separators for thousands are not used.

Symbols

Roche Diagnostics uses the following symbols and signs in addition to those listed in the ISO 15223-1 standard:

CONTENT	Contents of kit
→	Volume after reconstitution or mixing
GTIN	Global Trade Item Number

FOR US CUSTOMERS ONLY: LIMITED WARRANTY

Roche Diagnostics warrants that this product will meet the specifications stated in the labeling when used in accordance with such labeling and will be free from defects in material and workmanship until the expiration date printed on the label. THIS LIMITED WARRANTY IS IN LIEU OF ANY OTHER WARRANTY, EXPRESS OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR PARTICULAR PURPOSE. IN NO EVENT SHALL ROCHE DIAGNOSTICS BE LIABLE FOR INCIDENTAL, INDIRECT, SPECIAL OR CONSEQUENTIAL DAMAGES.

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