

Intended use

- Professional use
- Determination of one or more of the following parameters in urine: **Blood, Bilirubin, Urobilinogen, Ketones (Acetoacetic Acid), Protein, Nitrite, Glucose, pH, S.G (Specific Gravity), Leucocytes and Ascorbic Acid in urine.**

Warning and Precautions

URISCAN Urine Test Strips are for in vitro diagnostic use only. As with all laboratory tests, definitive Diagnostic or therapeutic decisions should not be based on any single strip or method. The effects of drugs or other metabolites on the individual tests are not known in all cases. It is therefore recommended that in doubtful cases, the test should be repeated after withdrawal of the medication and if results are questionable, repeat along with a confirmatory method.

Storage and Shelf life / Disposal

URISCAN Urine Test Strips are stable up to the expiry date specified on the label and box when stored in a room temperature and used according to the directions. Used test strip should be disposed according to the safety regulations applicable at your facility. The desiccant in the strip container is non-toxic for your health but if you inadvertently ingested it, you should flushed down with plenty of water.

Methodology

Blood	The test is based on pseudo-peroxidase reaction of hemoglobin. Oxygen is released, oxidizing tetramethylbenzidine, producing a color change from yellow through green to dark blue. The appearance of green spots on the reacted reagent area indicates the presence of intact RBC in the urine.
Bilirubin	This test is based on the coupling of bilirubin with diazotized dichloraniline in a strongly acid medium. The color range through various shades of pink to violet.
Urobilinogen	This test is based on the coupling of urobilinogen with diazotized p-methoxyaniline in a strongly acid medium. The colors range from beige through pink to dark pink.
Ketones	This test is based on the reaction of acetoacetic acid with nitroprusside, resulting in a color change from buff-pink to maroon.
Protein	This test is based on the color change of the indicator tetra bromophenol blue type in the presence of protein, producing a color change from yellow/green to blue.
Nitrite	This test is based on the conversion of nitrate to nitrite by the action of Gram negative bacteria in urine. At the acidic pH of the reagent area, nitrite in the urine reacts with sulfanilamide to form a diazonium compound. The diazonium compound couples with an aromatic compound to produce a pink color.
Glucose	This test is based on a double sequential enzyme reaction. One enzyme, glucose oxidase, catalyzes the formation of gluconic acid and hydrogen peroxide from the oxidation of glucose. A second enzyme, peroxidase, catalyzes the reaction of hydrogen peroxide with a potassium iodide chromogen to produce colors ranging from blue through green to brown.
pH	This test is based on a double indicator (methyl red and bromothymol blue) principle that gives a broad range of colors, from orange, yellow, green, and blue.
S.G (Specific Gravity)	This test is based on the pKa change of certain pretreated polymeric ion exchange resin in relation to ionic concentration. In the presence of an indicator, colors range from blue-green in urine of low ionic concentration through green and yellow-green in urines of increasing ionic concentration.
Leucocytes	This test is based on the color change ranging from beige to pink that occurs when esterase is hydrolyzed then coupled with diazonium salt to form a colored azo dye.
Ascorbic Acid	The composition comprises certain oxidized dye compounds which, in their oxidized state, are colored, but which become colorless when reduced by ascorbic acid.

For Visual

- 1 Protein(#U11), 1 Ketone(#U15), 1 Glucose(#U19), 2 GP(#U20), 3 GPH(#U21), 2 Gluketo(#U24)

For Visual or URISCAN Readers

- (Pro)Optima/S-300/Consult diagnostics(773)
- 5 HemoketoGPH(#U22), 6 L strip(#U25), 8 strip(#U26), 7 strip(#U27), 9 SG strip(#U37), 10SGL strip(#U39, #U774), 11strip(#U41) 5 Lstrip(#U46), 4 HemoGPH(#U12)

Composition

Blood	Tetramethylbenzidine 2,5-Dimethylhexane-2,5-dihydroperoxide	1.5mg 25mg
Bilirubin	2,4-Dichlorobenzene diazonium salt	0.65mg
Urobilinogen	Methoxybenzene diazonium salt	2.55mg
Ketones	Sodium nitroprusside	9.25mg
Protein	3,3',5'-Tetraiodophenolsulphonaphthalein	0.3mg
Nitrite	2-Aminobenzenesulfonamide Tetrahydrobenzquinoline	9.1mg 0.46mg
Glucose	Glucose oxidase Peroxidase Potassium iodide	0.315ku 0.05ku 7.0mg
pH	Methyl red Bromothymol blue	0.026mg 0.435mg
S.G	Bromothymol blue	0.7mg
Leucocytes	N-Tosylalanin indoxyleser	0.45mg
Ascorbic acid	2,6-Dichlorophenoldiphenol sodium salt	0.18mg

Specimen collection and Preparation

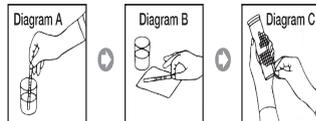
Use only clean dry container to collect urine and test it as soon as possible. If testing cannot be done within an hour after voiding, refrigerate the specimen immediately and let it return to room temperature before testing. The improperly stored/stored over 4 hours at RT, stored at high temperature (>30°C or >86°F) urine specimens may give inaccurate results.

Additional materials not provided: Absorbent paper (tissue or gauze), Timer (stopwatch), Clean dry container (tube or cup)

Test procedure

This procedure must be followed exactly to achieve reliable results.

- Please refer to the box and bottle label for specific reagent areas on the product you are using. Confirm that the product is within the expiration date shown on the label.
- Collect fresh, well-mixed, uncentrifuged urine specimen in a clean dry container. Mix well immediately before using.
- Remove one strip from the bottle and replace the cap immediately.
- Inspect the strip. If reagent areas are discolored, do not use the strip.
- Dip the test strip into the urine up to the last test pad for no more than 1 second.(See Diagram A)
- Wipe off excess urine on an absorbent paper. Lightly touch the edges of one side of the test strip on the absorbent paper. (See Diagram B.)
- Read the test results carefully at 60 seconds in a good light and with the test area held near the appropriate color chart on the bottle label. Changes in color that appear only along the edges of the test pads or after more than 2 minutes have passed are of no diagnostic significance. (See Diagram C.)
Results with leucocytes test portion can be read at 120 seconds.
If reading instrumentally, carefully follow the directions given in the appropriate instrument operating manual.



Handling procedure

Do not remove strip from the container before it is to be used for testing. Do not touch the test pads on the strip. After removing a test strip, immediately replace the cap completely. Do not remove the desiccant from the container.

Quality Control

For best results, performances of reagent strips should be confirmed by testing known negative and positive specimen or controls whenever a new bottle is first opened. Each laboratory should establish its own goals for adequate standards of performance. Each lab worker should ensure that it complies with government and local requirements.

Expected values

- Blood:** Negative by result; 2-3 red cells per high power field are generally accepted as normal by microscopy.
- Bilirubin:** Detectable amounts of bilirubin are not normally present in urine.
- Urobilinogen:** Male (0.3-2.1mg/2hours), Female(0.1-1.1mg/2hour), Result are sometimes expressed in Ehrlich units, 1 mg urobilinogen ≈ 1 EU
- Ketones:** In starvation diets or in other instances of abnormal carbohydrate metabolism, ketones appear in the urine in excessively large amounts before serum ketones are elevated.
- Protein:** Normally up to 20mg/dL of protein in the urine is not considered pathological.
- Nitrite:** Negative
- Glucose:** A small amounts of glucose (up to 30mg/dL) may be present in normal urine.
- pH:** 5-8, normal kidneys can produce urine with pH from 4.5-8.2, but with ordinary diet, urine pH is about 6.0
- S.G (Specific Gravity):** 1.003-1.029. Adult on normal fluid intake: 1.016-1.022, specific gravity decreases with increasing age.
- Leucocytes:** Normal urine ordinarily yield negative results.

Limitations of the method

- Blood:** Elevated SG or protein in urine may reduce the reactivity of the blood test portion. Oxidizing contaminants, such as hypochlorite, may produce false-positive results. Microbial peroxidase associated with urinary tract infection may cause a false-positive result. Higher ascorbic acid concentrations (>50mg/dL) may cause false-negative result at the low level of blood.
- Bilirubin:** Metabolites of drugs, such as Pyridium and Serenium, which give a color at low pH may cause false-positive. Indican(indoxyl sulfate) can produce a yellow-orange to red color response which may interfere with the interpretation of negative or positive readings. Ascorbic acid(>25mg/dL) may cause false-negative result.
- Urobilinogen:** The absence of urobilinogen in the specimen cannot be determined. The test area will react with substances known to derive Ehrlich's reaction, such as paraaminosalicylic acid. The test is not a reliable method for the detection of porphobilinogen.
- Ketones:** Highly pigmented or large amounts of levodopa metabolites containing urine may cause weak positive results. Some high-SG and low-pH urine may give false-positive result. P.S.P(phenolsulphonaphthalein) may cause false-positive result.
- Protein:** High alkaline urine(pH9) may cause false-positive result. Quinine,quinidine, chloroquine, trimethoprim, phenazopyridine,polyvinylpyrrolidone (blood substitutes) and the residues of disinfectants containing quaternary ammonium groups or chlorhexidine in the urinary vessel may cause false-positive.
- Nitrite:** Ascorbic acid(>25mg/dL) may cause false-negative result with low level of nitrite containing(<0.03mg) urine. The negative result does not always mean that the patient is free from bacteriuria. Negative result may occur when urinary tract infections are caused by organisms which do not contain nitrate reductase; when urine has not been retained in the bladder long enough/4 hours or more for reduction of nitrate to nitrite occur; or when dietary nitrate is absent.
- Glucose:** High SG(>1.020) with high pH urine and ascorbic acid(>50mg/dL) may cause false-negative result at the low level of glucose. Ketones reduce the sensitivity of the test. moderately high ketone level(>40mg/dL) may cause false-negative for specimens containing small amounts of glucose (<100mg/dL). Reactivity may be influenced by urine SG and temperature. If the color appears somewhat mottled at the higher glucose concentration, match the darkest color to the color block.
- pH:** If the excessive urine is remain on the strip because of improper test procedure, it is possible that the acidic buffer in protein portion comes out and affect the pH portion, then pH result may be decreased than the actual. This phenomenon is called "run-over effect".
- Specific Gravity:** Highly buffered alkaline urine may cause diminished result, whereas highly buffered acidic urine may cause slightly elevated result.
- Leucocytes:** Large urinary protein excretion(>500mg/dL) may cause false-negative result. Nitrofurantoin masks the reacted color to yellow. Tetraacycline may cause false-negative result at a low level of leucocytes. High concentration of glucose (>2000mg/dL) may diminish this reaction at a low level of leucocytes.
- Ascorbic Acid:** Alkaline urine (pH 8-9) may diminish the reaction.

Performance characteristics

	Sensitivity	Specificity
Blood	5RBC/μl or 3-5RBC/hpf (0.015mg/dL hemoglobin)	Intact RBC, Hemoglobin, Myoglobin
Bilirubin	0.5mg/dL Bilirubin	Bilirubin
Urobilinogen	Trace-1EU/dL	Urobilinogen
Ketones	5mg/dL Acetoacetic Acid, 70mg/dL Acetone	Acetoacetic Acid
Protein	10mg/dL Albumin	Albumin
Nitrite	0.05mg/dL Nitrite ion (10 ⁶ bacteria/mL)	Nitrite ion
Glucose	50mg/dL Glucose	Glucose
Leucocytes	10WBC/μl or 3-5WBC/hpf	Intact and lysed WBCs, histocytes
Ascorbic Acid	10mg/dL Ascorbic acid	Ascorbic Acid (vitamin C)

* HPF : High Power Field

References

- IVD : For in vitro diagnostic use
- LOT : Lot number
- Attention, See instructions for use
- Store at
- Do not reuse
- Authorized Representative
- Use by / Expiry date (YY/MM/DD)
- Manufacturer

Bibliography

- NCCLS(NATIONAL COMMITTEE FOR CLINICAL LABORATORY STANDARD) GP 16-A / ROUTINE URINALYSIS AND COLLECTION, TRANSPORTATION AND PRESERVATION OF URINE SPECIMENS ; INTERPRETATION GUIDELINE VOL. 12 - NO 26, DEC, 1992
- EUBERG, K.HELLINGS, R. JAGENBURG & A. KALLNER, GUIDELINES FOR EVALUATION OF REAGENT STRIPS. SCAND. J. CLIN. LAB. INVEST 1989 ; 49 ; 689 - 699.

Manufacturer
YD Diagnostics CORP.
 76, Seoni-ro, Idong-up, Cheoin-gu, Yongin-si,
 Gyeonggi-do, 17127, Republic of Korea
 Tel. 82-31-329-2000 / Fax. 82-31-329-2002

EC REP **CARE diagnostica Laborrenzenz GmbH**
 Weseler Str. 110, 46202 Voerde, Germany
 TEL : 49-281-94-40-40 / FAX : 49-281-94-40-10