



URiSCAN 2 ACR urine strips and URiSCAN 10 ACR urine strips

INTENDED USE

The URiSCAN Optima urine chemistry test system is intended for the in vitro qualitative and semi-quantitative measurement of the following parameters: blood, ketones (acetoacetic acid), protein, nitrite, glucose, pH, SG (specific gravity), leucocytes, albumin and creatinine and the determination of the ACR (albumin: creatinine ratio). These measurements are useful in the evaluation of renal, urinary and metabolic disorders. The URiSCAN Optima urine chemistry test system consists of the URiSCAN Optima urine analyzer and URiSCAN 2 ACR or URiSCAN 10 ACR urine strips. The URiSCAN Optima urine analyzer is intended to read the color change on the test pads found on the URiSCAN 10 ACR urine strips and URiSCAN 2 ACR urine strips and to display and print the results. The URiSCAN 10 ACR urine strips include test pads for the following parameters: blood, ketones (acetoacetic acid), protein, nitrite, glucose, pH, SG (specific gravity), leucocytes, albumin and creatinine. The URiSCAN 2 ACR urine strips include test pads for the following parameters: albumin and creatinine. The URiSCAN Optima urine chemistry test system is intended for prescription use only, in clinical laboratory and in point-of-care settings.

SUMMARY AND EXPLANATION

The URiSCAN 2 ACR urine strips and URiSCAN 10 ACR urine strips results may aid clinicians in the detection of patients at risk of developing kidney damage. The URiSCAN 2 ACR urine strips and URiSCAN 10 ACR urine strips include tests for albumin and creatinine in urine. The URiSCAN Optima urine analyzer determines the albumin to creatinine ratio (ACR) that is given in mg albumin per g or mmol creatinine. The URiSCAN Optima is a semi-quantitative urine analyzer useful in the evaluation of renal, urinary and metabolic disorders. Microalbuminuria is an important adverse predictor of glycemic outcomes in pre-diabetes that may progress over a span of a number of years to overt nephropathy characterized by the presence of larger amounts of the protein albumin leaking through the kidneys' filter mechanism into the urine. The URiSCAN Optima urine analyzer reads the test pads on the URiSCAN 2 ACR and 10 ACR urine strips; the results are displayed or printed.

INFORMATION REGARDING CLIA WAIVER

The URiSCAN 2 ACR strips (Albumin, Creatinine, and ACR [albumin creatinine ratio]) and URiSCAN 10 ACR strips (Blood, Ketones [Acetoacetic acid], Protein, Nitrite, Glucose, pH, SG [Specific Gravity], Leucocytes, Albumin, Creatinine and ACR [albumin creatinine ratio]) are CLIA Waived when run on the URiSCAN Optima urine analyzers. The URiSCAN Optima urine analyzers are CLIA waived only when used with YD Diagnostics reagent strips, manufactured by YD Diagnostics.

A certificate of CLIA waiver is required to perform these tests in a waived setting. To obtain a certificate of waiver, contact your state department of health or visit the CMS web site for an application, Form CMS-116. Failure to adhere to the instructions for use, including instructions for limitations, intended use, and performing quality control testing, is off-label use, resulting in these tests being categorized as high complexity and subject to all CLIA regulations.

TEST PRINCIPLE

Albumin	This test is based on albumin binding to sulfonephthalein dye, producing a color ranging from pale green to aqua blue.
Creatinine	This test is based on the peroxidase-like activity of a copper creatinine complex that catalyzes the reaction of hydroperoxide and chromogen, producing color change from yellow through green to blue.
* Tests continue below for 10 ACR strips only	
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.

Package insert to be used with the following products URiSCAN 2 ACR strip(#U64), 10 ACR strip(#U62)

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 tetrabromophenol 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 product 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 polymer 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.

REAGENTS

Albumin	Sulfonephthalein dye	0.64 mg
Creatinine	3,3',5,5'-Tetramethyl benzidine	4.32 mg
	2,5-Dimethylhexane-2,5-dihydroperoxide	12 mg
	Copper Sulfate-5H ₂ O	4.8 mg
* Tests continue below for 10 ACR strips only		
Blood	Tetramethylbenzidine 2,5-Dimethylhexane-2,5-dihydroperoxide	1.5 mg 25 mg
Ketones	Sodium nitroprusside	9.25 mg
Protein	3,3',5,5'-Tetraiodophenolsulphonphthalein	0.3 mg
Nitrite	2-Aminobenzenesulfonamide	9.1 mg
	Tetrahydrobenzoquinoline	0.46 mg
Glucose	Glucose oxidase	315 unit
	Peroxidase	50 unit
	Potassium iodide	7.0 mg
pH	Methyl red	0.026 mg
	Bromothymol blue	0.435 mg
S.G	Bromothymol blue	0.7 mg
Leucocytes	N-Tosylalanin indoxyleser	0.45 mg

WARNING AND PRECAUTIONS

The URiSCAN 2 ACR urine strips and URiSCAN 10 ACR urine 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 result 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. They have been determined to be nonhazardous under the guidelines issued by OSHA in 29 CFR 1910.1200(d).

Caution: Federal law restricts this device to sale by or on the order of a physician or other practitioner licensed by the law of the State in which he practices, to use or order the use of the device.

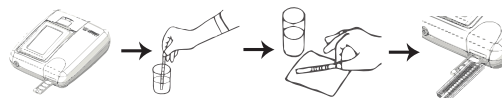
SPECIMEN COLLECTION AND PREPARATION

Use only a clean, dry container to collect urine and test it as soon as possible. Do not centrifuge. If testing cannot be done within an hour after voiding, refrigerate the specimen immediately and let it return to room temperature before testing. Improperly stored (stored over 4 hours at room temperature, stored at high temperature (>30°C or >86°F)) urine specimens may give inaccurate results. Specimens may be stored at -20°C for one month without significant effect on results. Additional materials (not provided): Absorbent paper (tissue or gauze), Clean dry container (tube or cup).

TEST PROCEDURE

This procedure must be followed exactly to achieve reliable results.

1. 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.
2. Collect fresh, well-mixed urine specimen in a clean, dry container. Mix well immediately before testing.
3. Remove one strip from the bottle and replace the cap immediately.
4. Inspect the strip. If reagent areas are discolored, do not use the strip.
5. **Read the strip on the URiSCAN Optima only:** Touch the word "Measure" after power on.
6. Dip the test strip into the urine up to the last test pad for no more than 1 second.
7. Immediately wipe off excess urine on an absorbent paper. Lightly touch the edges of one side of the test strip on the absorbent paper.
8. Place the reagent strip onto the instrument's strip holder without delay.
9. Touch the word "Start."
10. The strip holder is automatically pulled into the instrument, where the strip is identified and read. Results are displayed or printed as soon as they are available.
11. Record the results you obtain, then discard the strip into a suitable trash container.



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. Remove test strip from the container immediately before testing. After removal of the test strip, immediately replace the cap tightly. Do not remove the desiccant from the container. Store at relative humidity between 10-60%.

STORAGE AND STABILITY / DISPOSAL

The URiSCAN 2 ACR urine strips and URiSCAN 10 ACR urine strips are stable up to the expiry date specified on the label and box. Store at room temperature and relative humidity 10-60%. Do not use after expiration date.

Used test strips should be disposed according to the safety regulations applicable at your facility. The desiccant in the container is non-toxic for your health but if you inadvertently ingest it, you should drink plenty of water.

Rx only

QUALITY CONTROL

It is recommended to use commercially available liquid, ready-to-use controls intended for monitoring urine strip results for all test pads found on the strip to be tested.

- Test positive and negative quality controls under the following conditions:
- a. With each new shipment of reagent strips and every 30 days to check the storage of the reagent strips;
 - b. When using a new bottle of reagent strips;
 - c. When training instrument operators;
 - d. Whenever test results are in doubt;

Also, run QC tests per your laboratory's own test procedures. Do not use water as a negative control. All commercially available controls are composed of two levels (negative/low and positive).

An example of a commercially available control is the BioSys Plus Liquid Urine Controls.

CLIA WAIVED LABORATORIES

This test is waived under CLIA '88 regulations. If a laboratory modifies the test system instructions, then the test is considered high complexity and subject to all CLIA requirements.

A CLIA Certificate of Waiver is needed to perform CLIA waived testing. A Certificate of Waiver can be obtained from the Centers of Medicare & Medicaid Services (CMS). Please contact Technical Support at 626-403-6565 or email info@yd-diagnostics.com, or visit www.yd-diagnostics.com for assistance.

LIMITATIONS OF THE METHOD

- Blood : Elevated S.G 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 low level of blood in urine.
- Ketones: Highly pigmented urine or large amounts of levodopa metabolites containing urine may cause weak positive results. Some high S.G and low pH urine may give false-positive result. P.S.P. (phenolsulfonphthalein) may cause false-positive result.
- Protein : Highly alkaline urine (>pH9) may cause false-positive result. Quinine, quinidine, chloroquine, trimethoprim, phenazopyridine, polyvinyl-pyrrolidone (blood substitutes) and the residues of disinfectants containing quaternary ammonium groups or chlorhexidine in the urinary container for collection may cause false-positive.
- Nitrite : Ascorbic acid (>25mg/dL) may cause false-negative result with urine containing low level of nitrite (<0.03mg/dL) 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 organism which do not contain nitrate reductase ; when urine has not been retained in the bladder long enough (four hours or more) for reduction of nitrate to nitrite occur ; or when dietary nitrate is absent.
- Glucose : High S.G (>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 S.G 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 remains on the strip because of improper test procedure, then pH result may be higher than the actual value due to run over effect.
- Specific Gravity : Highly buffered alkaline urine may cause diminished result, whereas highly buffered acidic urine may slightly elevated result. This phenomenon is called "run-over effect"
- Leucocytes : Large urinary protein excretion (>500mg/dL) may cause false-negative result. Nitrofurantoin masks the reacted color to yellow. Tetracycline 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.

The following table shows the substances which did interfere with one or more of the albumin and creatinine test pads. The results indicated are the lowest concentration of the interfering substance, based on the change of output of color-block:

Analytes	Concentration of Substance at which Interference was observed	Change in Color Block Output
Albumin	Calcium chloride ≥ 200 mg/dL, Fructose ≥ 80 mg/dL, Ascorbic acid ≥ 300 mg/dL, Citric acid ≥ 55 mg/dL, Sodium nitrite ≥ 8 mg/dL, Potassium chloride ≥ 1200 mg/dL, Sodium chloride ≥ 5000 mg/dL, Riboflavin ≥ 15 mg/dL, High specific gravity ≥ 1.050	-1
	Sodium bicarbonate ≥ 1350 mg/dL, Phenolphthalein ≥ 1050 mg/dL, Theophylline ≥ 85 mg/dL, Sodium acetate ≥ 250 mg/dL, Acetaminophen ≥ 40 mg/dL, High pH \geq pH 9, Bilirubin ≥ 4 mg/dL, Hemoglobin ≥ 5 mg/dL, Blood ≥ 300 mg/dL	+1
Creatinine	Glycine ≥ 430 mg/dL, Sodium bicarbonate ≥ 1200 mg/dL, Sodium-2-mercaptoethane ≥ 510 mg/dL, High pH \geq pH 9	-1
	Calcium chloride ≥ 220 mg/dL, Sodium chloride ≥ 5200 mg/dL, Albumin ≥ 890 mg/dL, Theophylline ≥ 90 mg/dL	+1

Substances that cause abnormal urine color, such as drugs containing azo dyes (e.g., Pyridium, AZO Gantrisin, AZO Gantanol), nitrofurantoin (Macrochantin, Furadantin) and urinalysis reagent strips will affect the results. Urinary albumin excretions can be elevated by exercise, urinary tract infection, and acute illness with fever. It is recommended that individuals avoid strenuous exercise prior to testing.

TABLE OF RESULTS

The following table shows the results, in both conventional and SI units, which can be obtained when using the URISCAN Optima Analyzer.

Test	Printed/Displayed Results		
	Block	Conv. Units	S.I. Units
Albumin (Alb)	-	Neg.(0 mg/L)	10 mg/L
	1+	30 mg/L	30 mg/L
	2+	80 mg/L	80 mg/L
	3+	150 mg/L	150 mg/L
Creatinine (Cre)	++	10 mg/dL	0.9 mmol/L
	1+	50 mg/dL	4.4 mmol/L
	2+	100 mg/dL	8.8 mmol/L
	3+	200 mg/dL	17.7 mmol/L
	4+	300 mg/dL	26.5 mmol/L
Albumin to Creatinine Ratio(ACR)	<30 mg/g	<30 mg/g (Normal)	<3.4 mg/mmol (Normal)
	30-300 mg/g	30-300 mg/g (Abnormal)	3.4-33.9 mg/mmol (Normal)
	>300 mg/g	>300 mg/g (High Abnormal)	>33.9 mg/mmol (High Abnormal)
* Tests continue below for 10 ACR strips only			
Blood	-	Neg.	Neg.
	+	5 RBC/uL	5 RBC/uL
	1+	10 RBC/uL	10 RBC/uL
	2+	50 RBC/uL	50 RBC/uL
	3+	250 RBC/uL	250 RBC/uL
Ketones	-	Neg.	Neg.
	++	5 mg/dL	0.1 mmol/L
	1+	10 mg/dL	1 mmol/L
	2+	50 mg/dL	5 mmol/L
	3+	100 mg/dL	10 mmol/L
Protein	-	Neg.	Neg.
	+	10 mg/dL	0.1 g/L
	1+	30 mg/dL	0.3 g/L
	2+	100 mg/dL	1 g/L
	3+	300 mg/dL	3 g/L
Nitrite	-	Neg.	Neg.
	+	Pos.	Pos.
Glucose	-	Neg.	Neg.
	++	100 mg/dL	5.5 mmol/L
	1+	250 mg/dL	14 mmol/L
	2+	500 mg/dL	28 mmol/L
	3+	1000 mg/dL	55 mmol/L
	4+	2000 mg/dL	111 mmol/L

Test	Printed/Displayed Results		
	Block	Conv. Units	S.I. Units
pH	5.0	5.0	5.0
	5.5	5.5	5.5
	6.0	6.0	6.0
	6.5	6.5	6.5
	7.0	7.0	7.0
	7.5	7.5	7.5
	8.0	8.0	8.0
	8.5	8.5	8.5
SG	≤ 1.005	≤ 1.005	≤ 1.005
	1.010	1.010	1.010
	1.015	1.015	1.015
	1.020	1.020	1.020
	1.025	1.025	1.025
	1.030 \leq	1.030 \leq	1.030 \leq
Leucocytes	-	Neg.	Neg.
	++	10 WBC/uL	10 WBC/uL
1+	25 WBC/uL	25 WBC/uL	
2+	75 WBC/uL	75 WBC/uL	
3+	500 WBC/uL	500 WBC/uL	

EXPECTED VALUES

- **Albumin:** Albumin is normally present in urine at concentrations of less than 20 mg/L.¹⁴ Moderately increased albuminuria is defined as an albumin excretion rate of 30 ~ 299 mg/24 hours.^{15, 16} Urinary albumin excretions can be temporarily elevated by exercise, urinary tract infections, and acute illness with fever.

- **Creatinine :** Creatinine is normally present in urine. There are no established reference values for creatinine in the urine however can be used to normalize other analytes found in a random urine sample at concentrations of 10 to 300 mg/dL (0.9 ~ 26.5 mmol/L).

► **Albumin to Creatinine Ratio:** Albumin to Creatinine Ratio is normally at less than 30 mg albumin/g creatinine (3.4 mg albumin /mmol creatinine). Moderately increased albuminuria is indicated at a ratio result of 30 ~ 300 mg/g (3.4 ~ 33.9 mg/mmol) and severely increased albuminuria at a ratio result of > 300 mg/g (> 33.9 mg/mmol).¹³

* Tests continue below for 10 ACR strips only

- **Blood :** Normally, no hemoglobin is detectable in urine.
- **Ketones :** Ketones should not be detected in normal urine.
- **Protein :** Normally less than 10-20mg/dL(150 mg/day) of protein in the urine is not considered pathological.
- **Nitrite :** Negative
- **Glucose :** Glucose is typically not found in urine unless the serum glucose exceeds a certain level (e.g. 180 mg/dL) or at times during pregnancy.
- **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. Specific gravity may decrease with increasing age.
- **Leucocytes :** Normal urine ordinarily yield negative results.

SPECIFIC PERFORMANCE CHARACTERISTICS

Accuracy :

The total of 407 random urine specimens were collected and used for the comparative study. The urine samples were tested with the 10ACR strips (candidate device) and predicate device. All testing was performed in a blinded fashion. The summarized results are below as.

Albumin test : Positive percent agreement 100.0%, Negative percent agreement 100.0%. Creatinine test : All percent agreement 96.3%. ACR (albumin : creatinine ratio) test : Positive percent agreement 98.5%, Negative percent agreement 98.6%. Blood test : Positive percent agreement : 99.4%, Negative percent agreement : 98.3%. Ketones test : Positive percent agreement : 98.1%, Negative percent agreement : 98.7%. Protein test : Positive percent agreement : 98.3%, Negative percent agreement : 99.1%. Nitrite test : Positive percent agreement : 100.0%, Negative percent agreement : 99.7%. Glucose test : Positive percent agreement : 99.3%, Negative percent agreement : 98.5%. pH test : All percent agreement : 95.3%. SG test : All percent agreement : 95.1%. Leucocytes test : Positive percent agreement : 99.3%, Negative percent agreement : 98.4%.

Precision :

Urine control at known concentrations were assayed at different two levels at three clinical sites. The following percents of replicate reading were obtained. Percents agreement of replicate reading in blood, ketones, protein, nitrite, glucose, pH, SG, leucocytes, albumin, creatinine and ACR : 100%

CAUTION

1. This product is for in vitro diagnostic use only.
2. Strips are to be read on the URISCAN Optima Urine analyzer, not for visual read. Carefully read and follow all instructions in the Operator's Manual for the URISCAN Optima Urine analyzer.
3. Protect the URISCAN 2 ACR urine strips and URISCAN 10 ACR urine strips against moisture, light and heat to guard against altered reagent reactivity.
4. Store in cool and dry place. Do not store in refrigerator.
5. Do not remove desiccant packet (s) from bottle.
6. Remove each strip from the bottle immediately before it is to be used and replace cap immediately and tightly.
7. Do not touch test areas of the reagent strip and don't place the strip on the desk or test table to avoid contamination of strip.
8. If reagent areas are discolored, do not use the strip.
9. Dip test pad areas in urine completely, but briefly, to avoid dissolving the reagents.
10. If testing cannot be done within one hour after voiding, refrigerate the specimen immediately and let it return to room temperature before testing.

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TECHNICAL ASSISTANCE

For technical support, contact your local technical support provider or distributor. In the US call: 626-403-6565 or e-mail: info@yd-diagnostics.com or visit www.yd-diagnostics.com

REFERENCE

- IVD** : For in vitro diagnostic use  : Use by / Expiry date
 : Attention, See instructions for use **LOT** : Lot number
 : Do not reuse  : Store at **Cont.** : Contents of kit
 : Manufacturer **EC REP** : Authorized Representative
CE : European Conformity

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