URiSCAN®

IVD

ACR Strips

Package insert to be used with the following products
URiSCAN 2 ACR strip(#U64), 10 ACR strip(#U62), 11 ACR strip(#U63)

INTENDED USE

The intended use of the URiSCAN ACR strips is for the in vitro semi-quantitative measurement of the following parameters: Blood, Ketones (Acetoacetic acid), Protein, Nitrite, Glucose, pH, SG (specific gravity), Leucocytes, Ascorbic acid, Albumin, Creatinine and ACR (albumin creatinine ratio).
These measurements are useful in the evaluation of renal, urinary and metabolic disorders. The URiSCAN ACR strips are intended for prescription use only, in clinical laboratory and in point-of-care settings.

SUMMARY AND EXPLANATION

The URiSCAN ACR strips test results may aid clinicians in the detection of patients at risk of developing kidney damage. The URiSCAN ACR strips include two parameters that test for albumin and creatinine in urine. The URiSCAN urine analyzer determines the albumin to creatinine ratio (ACR) that is given in mg albumin per *g* or *mmol* creatinine. The URiSCAN urine analyzer 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.

TEST PRINCIPLE

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.
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 tetrabromphenol 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 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.
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.

REAGENTS

100 tests

Blood	Tetramethylbenzidine 2,5-Dimethylhexane-2,5-dihydroperoxide	1.5mg 25mg
Ketones	Sodium nitroprusside	9.25mg
Protein	3,3',5,5'-Tetraiodophenolsulphonephthalein	0.3mg
Nitrite	2-Aminobenzenesulfonamide Tetrahydrobenzoquinoline	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-Dichlorophenolindophenol sodium salt	0.18mg
Albumin	Sulfonphthalein dye	0.64 mg
Creatinine	3,3',5,5'-Tetramethyl benzidine 2,5-Dimethylhexane-2,5-dihydroperoxide Copper Sulfate·5H_2O	4.32 mg 12 mg 4.8 mg

WARNING AND PRECAUTIONS

URiSCAN ACR 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.

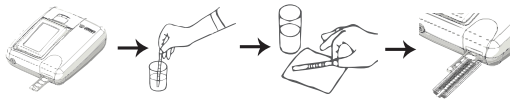
SPECIMEN COLLECTION AND PREPARATION

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℃ or >86℉]) urine specimens may give inaccurate results. Specimens may be stored at - 20℃ 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 :** 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

URiSCAN ACR 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.

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).

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, polyvinylprolidone (blood substituents) and the residues of disinfectants containing quaternary ammonium groups or chlorohexidine 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.
- 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.
- Ascorbic Acid : Alkaline urine (pH 8~9) may diminish the reaction.

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 ≥200mg/dℓ, Fructose ≥80mg/dℓ, Ascorbic acid ≥300mg/dℓ, Citric acid ≥65mg/dℓ, Sodium nitrite ≥8mg/dℓ, Potassium chloride ≥1200mg/dℓ, Sodium chloride ≥5000mg/dℓ, Riboflavin ≥15mg/dℓ, High specific gravity ≥1.050	-1
	Sodium bicarbonate ≥1350mg/dℓ, Phenolphthalein ≥1050mg/dℓ, Theophylline ≥85mg/dℓ, Sodium acetate ≥250mg/dℓ, Acetaminophen ≥40mg/dℓ, High pH ≥pH 9, Bilirubin ≥4mg/dℓ, Hemoglobin ≥5mg/dℓ, Blood ≥300mg/dℓ	+1
Creatinine	Glycine ≥430mg/dℓ, Sodium bicarbonate ≥1200mg/dℓ, Sodium-2-mercaptoethene ≥510mg/dℓ, High pH ≥pH 9	-1
	Calcium chloride ≥220mg/dℓ, Sodium chloride ≥5200mg/dℓ, Albumin ≥890mg/dℓ, Theophylline ≥90mg/dℓ	+1

Substances that cause abnormal urine color, such as drugs containing azo dyes (e.g., Pyridium, AZO Gantrisin, AZO Gantanol), nitrofurantoin (Macrodantin, 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 Urine Analyzer.

Test	Printed/Displayed Results		
	Block	Conv. Units	S.I. Units
Blood	-	Neg.	Neg.
	+- 1+ 2+ 3+	5 RBC/uL 10 RBC/uL 50 RBC/uL 250 RBC/uL	5 RBC/uL 10 RBC/uL 50 RBC/uL 250 RBC/uL
Ketones	-	Neg.	Neg.
	+- 1+ 2+ 3+	5 mg/dL 10 mg/dL 50 mg/dL 100 mg/dL	0.1 mmol/L 1 mmol/L 5 mmol/L 10 mmol/L

Test	Printed/Displayed Results		
	Block	Conv. Units	S.I. Units
Protein	-	Neg.	Neg.
	+- 1+ 2+ 3+ 4+	10 mg/dL 30 mg/dL 100 mg/dL 300 mg/dL 1000 mg/dL	0.1 g/L 0.3 g/L 1 g/L 3 g/L 10 g/L
Nitrite	-	Neg.	Neg.
	+	Pos.	Pos.
Glucose	-	Neg.	Neg.
	+- 1+ 2+ 3+ 4+	100 mg/dL 250 mg/dL 500 mg/dL 1000 mg/dL 2000 mg/dL	5.5 mmol/L 14 mmol/L 28 mmol/L 55 mmol/L 111 mmol/L
pH	5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 9.0	5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 9.0	5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 9.0
SG	≤1.005 1.010 1.015 1.020 1.025 1.030≤	≤1.005 1.010 1.015 1.020 1.025 1.030≤	≤1.005 1.010 1.015 1.020 1.025 1.030≤
Leucocytes	-	Neg.	Neg.
	+- 1+ 2+ 3+	10 WBC/uL 25 WBC/uL 75 WBC/uL 500 WBC/uL	10 WBC/uL 25 WBC/uL 75 WBC/uL 500 WBC/uL
Ascorbic acid	-	Neg.	Neg.
	1+ 2+ 3+	10 mg/dL 25 mg/dL 50 mg/dL	0.6 mmol/L 1.4 mmol/L 2.8 mmol/L
Albumin (Alb)	-	Neg.(0 mg/L)	10 mg/L
	1+ 2+ 3+	30 mg/L 80 mg/L 150 mg/L	30 mg/L 80 mg/L 150 mg/L
Creatinine (Cre)	+- 1+ 2+ 3+ 4+	10 mg/dL 50 mg/dL 100 mg/dL 200 mg/dL 300 mg/dL	0.9 mmol/L 4.4 mmol/L 8.8 mmol/L 17.7 mmol/L 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 (Abnormal)
	>300 mg/g	>300 mg/g (High Abnormal)	>33.9 mg/mmol (High Abnormal)

EXPECTED VALUES

- **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 :1.016~1.022, specific gravity decreases with increasing age.
- **Leucocytes :** Normal urine ordinarily yield negative results.

EXPECTED VALUES

- **Albumin:** Albumin is normally present in urine at concentrations of less than 20 mg/L.[14] Microalbuminuria 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 at concentrations of 10 to 300 mg/dL (0.9 ~ 26.5 mmol/L)
- ▶ **Albumin to Creatinine Ratio:** Albumin is normally present in urine at concentrations of less than 30 mg albumin/g creatinine (3.4 mg albumin /mmol creatinine). Microalbuminuria is indicated at a ratio result of 30 ~ 300 mg/g (3.4 ~ 33.9 mg/mmol) and clinical albuminuria at a ratio result of > 300 mg/g (> 33.9 mg/mmol).[13]

SPECIFIC PERFORMANCE CHARACTERISTICS

The performance characteristics are based on clinical and analytical tests. The evaluation followed "Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline (2002) NCCLS, EP9A." The clinical studies tested 351 urine samples. The performance characteristics of the URiSCAN 2ACR Urine strips test on the URiSCAN Optima were compared with SIEMENS CLINITEK Microalbumin 2 on the CLINITEK Status instrument at multiple hospital sites.

Accuracy: The following table shows the summary comparative results of albumin to creatinine test.

ACR (Site A, n=351)		Predicate device (mg/g)		
		<30	30-300	>300
New device	>300	0	0	57
(mg/g)	30-300	2	169	1
	<30	118	4	0
Total		120	173	58
Exact agreement (%)		98.3%	97.7%	98.3%
Within One Block (%)		100%	100%	100%

A total of 351 random urine specimens were collected and used in a comparative study for albumin and creatinine using the SIEMENS CLINITEK Microalbumin system and the URiSCAN Optima system. Percent agreement with SIEMENS CLINITEK Microalbumin system for albumin test: 95.7%, Positive Agreement: 100.0%, Negative Agreement: 100.0%. Percent agreement with SIEMENS CLINITEK Microalbumin system for creatinine test: 96.6%. Percent agreement with SIEMENS CLINITEK Microalbumin system for ACR (albumin:creatinine ratio) test: 97.7%, Positive Agreement: 97.8%, Negative Agreement: 98.3%.

Precision: Ten replicates of urine specimens at known concentrations were assayed at different five levels at three Clinical sites. The following percents of replicate reading were obtained. Percents agreement of replicate reading in albumin, creatinine, ACR: 100%

CAUTION

1. This product is for in vitro diagnostic use only.
2. Carefully read and follow all instructions in the Operator's Manual for the URiSCAN Urine analyzer.
3. Protect the URiSCAN ACR 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.
11. Do not cut the test strip.

BIBLIOGRAPHY

1. Zhang QL and Rothenbacher D. Prevalence of chronic kidney disease in population-based studies : systemic review. BMC Public Health 2008;8:117
2. Keane WF and Eknoyan G. Proteinuria, albuminuia, risk, assessment, detection, elimination (PARADE): A position paper of the National Kidney Foundation. Am J Kidney Dis 1999;33:1004-10.
3. Sacks DB, Arnold M, Bakris GL, Bruns DE, Horvath AR, Kirkman MS, et al. Position statement executive summary: guidelines and recommendations for laboratory analysis in the diagnosis and management of diabetes mellitus. Diabetes Care 2011;34:1419-23.
4. Hishi S, Tochikubo O, Miyjima E, Ishi M. Circadian variation of urinary microalbumin excretion and ambulatory blood pressure in patients with essential hypertension. J Hypertens 1998;16:2101-8.
5. Levey AS, Eckardt KU, Tsukamoto Y, Levin A, Coresh J, Rossert J, et al. Definition and classification of chronic kidney disease: a position statement from Kidney Disease: Improving Global Outcomes (KDIGO). Kidney Int 2005;67:2089-100.
6. Wilde HM, Banks D, Larsen CL, Connors G, Wallace D, Lyon ME. Evaluation of the Bayer® microalbumin/creatinine urinalysis dipstick. Clinica Chimica Acta 2008;393:110–3.
7. Guy M, Newall R, Borzomato J, Kalra PA, Price C. Diagnostic accuracy of the urinary albumin: creatinine ratio determined by the CLINITEK Microalbumin and DCA 2000+ for the rule-out of albuminuria in chronic kidney disease. Clin Chim Acta 2009;399:54-8.
8. Omoruyi FO, Mustafa GM, Okorodudu AO, Petersen JR. Evaluation of the performance of urine albumin, creatinine and albumin-creatinine ratio assay on two POCT analyzers relative to a central laboratory method. Clin Chim Acta 2012;413:625-9.
9. McTaggart MP, Price CP, Pinnock RG, Stevens PE, Newall RG, Lamb EJ. The diagnostic accuracy of a urine albumin-creatinine ratio point-of-care test for detection of albuminuria in primary care. Am J Kidney Dis 2012;60:787-94.
10. Mogensen CE. Prevention of diabetic renal disease with special reference to microalbuminuria. Lancet 1995;346:1080-4.
11. NCCLS (NATIONAL COMMITTEE FOR CLINICAL LABORATORY STANDARD) GP 16 – A / ROUTINE URINALYSIS AND COLLECTION, TRANSPORATION AND PRESEVATION OF URINE SPECIMENS ; APPROVED GUIDELINE NO 15. 1995
12. B.BERG, K.HELLSING, R. JAGENBURG & A. KALLNER. GUIDELINES FOR EVALUATION OF REAGENT STRIPS. SCAND. J. CLIN. LAB. INVEST 1989 ; 49 ; 689 - 699.
13. Position Statement: Diabetic Nephropathy. Diabetes Care 20: S24-S27; 1997.
14. Burtis, C.A. and Ashwood, E.R.: Tietz Textbook of Clinical Chemistry, 3rd ed. Philadelphia: Saunders; 1999; pp. 483-484.
15. Mangili, R. et al.: Prevalence of Hypertension and Microalbuminuria in Adult Type 1(Insulin Dependent) Diabetic Patients without Penal Failure in Italy – Validation of Screening.
16. American Diabetes Association, Clinical Practice Recommendations, Diabetes Care, Vol. 31, Suppl. 1, January 2008.

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

YD Diagnostics

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

EC REP **CARE diagnostica Laborreagenzien GmbH**
Weseler Str. 110, 46562 Voerde, Germany
TEL : 49-281-94-40-40 / FAX : 49-281-944-04-10

CE

Rev.03/2022-09-02