

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION  
DECISION MEMORANDUM  
ASSAY AND INSTRUMENT COMBINATION TEMPLATE**

**A. 510(k) Number:**

k141874

**B. Purpose for Submission:**

New device

**C. Measurand:**

Urine Creatinine and Albumin

**D. Type of Test:**

Semi-quantitative colorimetric urinalysis

**E. Applicant:**

YD Diagnostics Corp.

**F. Proprietary and Established Names:**

URiSCAN 2ACR Urine strips  
URiSCAN Optima Urine Analyzer

**G. Regulatory Information:**

Product Code	Classification	Regulation Section	Panel
JFY	Class II	21 CFR 862.1225 Creatinine test system.	Chemistry (75)
JIR	Class I	21 CFR 862.1645 Urinary protein or albumin (nonquantitative) test system	Chemistry (75)
KQO	Class I	21 CFR 862.2900 Automated urinalysis system	Chemistry (75)

## H. Intended Use:

1. Intended use(s):

Refer to Indications for use below.

2. Indication(s) for use:

The URiSCAN Optima urine chemistry test system consists of URiSCAN Optima Urine analyzer and URiSCAN 2ACR Urine strips. The intended use of the URiSCAN Optima Urine analyzer is to read the color change on the test pads found on the URiSCAN 2ACR Urine strips and to display and print the results.

The intended use of the URiSCAN 2ACR Urine test strips is for the in vitro semi-quantitative measurement of the following parameters:

Albumin  
Creatinine  
ACR (Albumin Creatinine Ratio)

These measurements are useful in the evaluation of renal, urinary and metabolic disorders. URiSCAN Optima urine chemistry test system is intended for prescription use only, in clinical laboratory and in point-of-care setting.

3. Special conditions for use statement(s):

This product is for in vitro diagnostic use only.

Not for visual read.

4. Special instrument requirements:

URiSCAN Optima Urine analyzer

## I. Device Description:

The URiSCAN 2ACR Urine strip is a plastic strip with color blocks that can semi-quantitatively measure albumin and creatinine simultaneously using chemical reactions. The Albumin – Creatinine Ratio (ACR) results are based on the color changes obtained on the measurements of albumin and creatinine.

The URiSCAN Optima Urine analyzer is a semi-quantitative urine analyzer used to determine the amounts of components in urine including albumin, creatinine and ACR (albumin creatinine ratio), represent the figures on a liquid crystal display and through a printer and transfer them to a computer.

**J. Substantial Equivalence Information:**

1. Predicate device name(s):

Siemens Clinitek Status

2. Predicate 510(k) number(s):

k091216

3. Comparison with predicate:

Similarities		
Item	URiSCAN 2ACR Urine strips and URiSCAN Optima Urine Analyzer (Candidate Device)	Clinitek Status (Predicate Device K971216)
Intended Use	Intended for the semi-quantitative urine measurement of the following parameters: albumin, creatinine and ACR (albumin creatinine ratio).	Same
Measuring Range	10-150mg/L albumin 10-300 mg/dL creatinine	Same
Sample Type	Urine	Same
Format	Strips	Same

Differences		
Item	URiSCAN 2ACR Urine strips and URiSCAN Optima Urine Analyzer (Candidate Device)	Clinitek Stratus (Predicate Device K972706)
Analytes	Albumin, Creatinine	Albumin, Creatinine, Glucose, Blood (Occult), human Chorionic Gonadotropin (hCG), Creatinine, Albumin, Protein, Bilirubin, Ketone, Leukocytes, Nitrite, pH, Specific Gravity, and Urobilinogen
Throughput	36 tests/hour	50 tests/hour
Measuring Cycle	100sec	70sec

**K. Standard/Guidance Document Referenced (if applicable):**

CLSI EP5-A2 Evaluation of Precision Performance of Quantitative Measurement Methods” Approved Guideline – Second Edition.

CLSI EP7-A Interference testing in clinical chemistry; Approved Guideline.

CLSI EP9A Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline (2002).

**L. Test Principle:**

The urine will be absorbed into each test portion of the strip and the subsequent chemical and enzymatic reactions will change the color of the test paper in proportion to the amount of analyte present in the sample. The reaction for the albumin test is based on dye binding using a sulfonephthalein dye. At a constant pH, albumin binds sulfonephthalein dye. The resulting color on the test pad ranges from pale green to aqua blue.

The reaction for the creatinine test is based on the peroxidase-like activity of a copper creatinine complex that catalyzes the reaction of cummen hydroperoxide and 3,3',5,5'-tetramethylbenzidine. The resulting color on the test pad ranges from yellow through green to blue.

The analyzer, a charge coupled device, will measure and analyzes the ratios of the composition of the primary colors of light, and reads out the extent of change in the color of the test paper.

**M. Performance Characteristics (if/when applicable):**

1. Analytical performance:

a. *Precision/Reproducibility:*

Within-run precision:

Two within run studies were performed; one using 2 levels of controls for each analyte and one using urine samples for each analyte. The studies were performed at 3 different clinical sites using 3 lots of URiSCAN 2 ACR strips and 10 replicates for a total of 90 reps per level for each analyte. Three different URiSCAN Optima analyzers were also used. The control concentrations used are as follows: albumin control level 1 ( $\leq 10\text{mg/L}$ ) and control level 2 ( $80 - \geq 150\text{mg/L}$ ); creatinine control level 1 ( $10 - 50\text{mg/dL}$ ) and control level 2 ( $100 - \geq 300\text{mg/dL}$ ) were used for the studies. The urine samples were spiked at 4 levels of albumin as follows:  $-(0\text{mg/L})$ ,  $+(30\text{mg/L})$ ,  $2+(80\text{mg/L})$ ,  $3+(150\text{mg/L})$  and at the following 5 levels of creatinine:  $\pm(10\text{mg/dL})$ ,  $+(50\text{mg/dL})$ ,  $2+(100\text{mg/dL})$ ,  $3+(200\text{mg/dL})$  and  $4+(300\text{mg/dL})$ .

Results were consistent between lots. A representative lot results are presented in the tables below:

Control Samples:

Within-run test (n=10)	Level 1			Level 2		
	ALB	CRE	ACR	ALB	CRE	ACR
Target Value	-	±	<30mg/g	3+	4+	>300 mg/g
Agreement within same grade (%)	100% (10/10)	100% (10/10)	100% (10/10)	100% (10/10)	100% (10/10)	100% (10/10)

Albumin Urine Samples:

Within-run N=50	ALB	ALB	ALB	ALB
Target Value	-	+	2+	3+
Agreement within same grade (%)	100% (50/50)	100% (50/50)	100% (50/50)	100% (50/50)

Creatinine Urine Samples:

Within-run N=50	CRE	CRE	CRE	CRE	CRE
Target value	±	+	2+	3+	4+
Agreement within same grade (%)	100% (50/50)	100% (50/50)	100% (50/50)	100% (50/50)	100% (50/50)

Albumin Creatinine Ratio (ACR) Urine Samples:

Within-run N=50	ACR	ACR	ACR	ACR	ACR
Target value	<30mg/g	30-300 mg/g	30-300 mg/g	30-300 mg/g	<30 mg/g
Agreement within same grade (%)	100% (50/50)	100% (50/50)	100% (50/50)	100% (50/50)	100% (50/50)

Intermediate precision:

Within day precision studies were performed using 2 levels of controls for each analyte and urine samples for each analyte. Each of the studies used three different URiSCAN Optima analyzers and three different lots of URiSCAN 2 ACR strips for 10 days. The test was performed at three different point-of-care (POC) sites by trained medical technicians. The control concentrations used are as follows: albumin control level 1 ( $\leq 10\text{mg/L}$ ) and control level 2 ( $80 - \geq 150\text{mg/L}$ ); creatinine control level 1 (10

- 50mg/dL) and control level 2 (100 -  $\geq$ 300mg/dL) were used for the studies. The urine samples were spiked at 4 levels of albumin as follows: -(0mg/L), +(30mg/L), 2+(80mg/L), 3+(150mg/L) and at the following 5 levels of creatinine:  $\pm$ (10mg/dL), +(50mg/dL), 2+ (100 mg/dL), 3+(200mg/dL) and 4+(300mg/dL) . Results were consistent between lots. A representative lot results are presented in the tables below:

Controls:

Intermediate precision (n=10)	Level 1			Level 2		
	ALB	CRE	ACR	ALB	CRE	ACR
Target Value	-	$\pm$	<30mg/g	3+	4+	>300 mg/g
Agreement within same grade (%)	100%	100%	100%	100%	100%	100%

Urine samples:

Albumin:

Intermediate precision N=50	ALB	ALB	ALB	ALB
Target value	-	+	2+	3+
Agreement within same grade (%)	100%	100%	100%	100%

Creatinine:

Within-run N=50	CRE	CRE	CRE	CRE	CRE
Target value	$\pm$	+	2+	3+	4+
Agreement within same grade (%)	100%	100%	100%	100%	100%

Albumin – Creatinine Ratio (ACR)

Within-run N=50	ACR	ACR	ACR	ACR	ACR
Target value	<30mg/g	30-300mg/g	30-300mg/g	30-300mg/g	<30mg/g
Agreement within same grade (%)	100%	100%	100%	100%	100%

b. *Linearity/assay reportable range:*

This assay reports color block outputs of 0mg/L (Negative), 30 mg/L, 80 mg/L, 150 mg/L for albumin, and 10 mg/dL, 50 mg/dL, 100 mg/dL, 200 mg/dL, 300 mg/dL for creatinine.

A study to evaluate the percent recovery was performed on 3 instruments using 3 lots of test strips, 5 test per strip lot on each instrument at 4 levels of albumin: negative, + (30mg/dL), 2+(80mg/dL), 3+(150 mg/dL) and 5 levels of creatinine: Trace (10mg/dL), 1+ (50mg/dL), 2+(100mg/dL), 3+(200 mg/dL) and 4+(300mg/dL). Results are summarized below.

Analyte	Color block Out-put	Concentration tested	% Match
Albumin	-(Neg.)	0 mg/L	100% (45/45)
	+	30 mg/L	100% (45/45)
	2+	80 mg/L	100% (45/45)
	3+	150 mg/L	100% (45/45)
Creatinine	± (Trace)	10mg/dL	100% (45/45)
	+	50 mg/dL	100% (45/45)
	2+	100 mg/dL	100% (45/45)
	3+	200 mg/dL	100% (45/45)
	4+	300 mg/dL	100% (45/45)

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*

The firm stated that the albumin strips are traceable to the CRM 475 from IFCC and the Creatinine is traceable to SRM 914a from NIST. The strips are prepared from commercial stocks and verified using commercial verifiers. The traceability for albumin and creatinine is then verified by turbidimetric immunoassay using the corresponding standard.

Stability protocol and acceptance criteria were reviewed and found acceptable and support the following stability claims: the strip can be stored at 15-30°C (59-86°F) and relative humidity of 10-60% in the closed package for up to 24 months and after opening for at least 3 months.

d. *Detection limit:*

The cutoff of the assay at each color block was validated by spiking or diluting a pooled urine sample with albumin and creatinine to achieve 3 levels of albumin and 4 levels of creatinine. Each level was further adjusted to concentrations below and above the midpoint concentration of each of these levels. Each sample was tested using 3 lots of strips on 3 analyzers. Each level was tested in replicates of 10. The cutoffs for each color block are defined as the lowest and highest concentrations of analyte tested at which over 50% of the results are positive for each color block. Results for each concentration tested at each color block are shown below:

Analyte	Concentrations tested	Percentage Agreement at Each Color Block			
		- (0 ml/L)	+ (30 ml/L)	2+ (80 ml/L)	3+ (150 ml/L)
Albumin	200 ml/L	0%	0%	0%	100%
	150 ml/L	0%	0%	0%	100%
	125 ml /L	0%	0%	0%	100%
	120 ml /L	0%	0%	0%	100%
	116 ml /L	0%	0%	25.6%	74.4%
	110 ml /L	0%	0%	70%	30%
	105 ml /L	0%	0%	100%	0%
	65 ml /L	0%	0%	100%	0%
	60 ml /L	0%	0%	100%	0%
	56 ml /L	0%	25.3%	74.7%	0%
	50 ml /L	0%	60%	40%	0%
	45 ml /L	0%	100%	0%	0%
	30 ml /L	0%	100%	0%	0%
	25 ml /L	0%	100%	0%	0%
	20 ml /L	25.6%	74.4%	0%	0%
15 ml /L	70%	30%	0%	0%	
10 ml /L	100%	0%	0%	0%	

Analyte	Concentrations tested	Percentage Agreement at Each Color Block				
		± (10ml/dL)	+ (50 ml/dL)	2+ (100 ml/dL)	3+ (200 ml/dL)	4+ (300 ml/dL)
Creatinine	350 ml/dL	0%	0%	0%	0%	100%
	300 ml/dL	0%	0%	0%	0%	100%
	290 ml/dL	0%	0%	0%	0%	100%
	285 ml/dL	0%	0%	0%	0%	100%
	281 ml/dL	0%	0%	0%	41.2%	58.8%
	275 ml/dL	0%	0%	0%	70%	30%
	270 ml/dL	0%	0%	0%	100%	0%
	190 ml/dL	0%	0%	0%	100%	0%
	185 ml/dL	0%	0%	0%	100%	0%

Analyte	Concentrations tested	Percentage Agreement at Each Color Block				
		± (10ml/dL)	+ (50 ml/dL)	2+ (100 ml/dL)	3+ (200 ml/dL)	4+ (300 ml/dL)
	181 ml/dL	0%	0%	43.3%	56.7%	0%
	175 ml/dL	0%	0%	80%	20%	0%
	170 ml/dL	0%	0%	100%	0%	0%
	90 ml/dL	0%	0%	100%	0%	0%
	85 ml/dL	0%	0%	100%	0%	0%
	81 ml/dL	0%	43.3%	56.7%	0%	0%
	75 ml/dL	0%	80%	20%	0%	0%
	70 ml/dL	0%	100%	0%	0%	0%
	40 ml/dL	0%	100%	0%	0%	0%
	35 ml/dL	0%	100%	0%	0%	0%
	30 ml/dL	43.3%	56.7%	0%	0%	0%
	25 ml/dL	80%	20%	0%	0%	0%
	20 ml/dL	100%	0%	0%	0%	0%

Summary of the performance at each color block for the tested analyte concentrations:

Analyte	Block output	Block cut-off value	% positive results
Albumin	+ (30ml/L)	20ml/L	74.4%
	2+ (80ml/L)	56 ml/L	74.7%
	3+ (150ml/L)	116ml/L	74.4%
Creatinine	+ (50ml/dL)	30ml/L	56.7%
	2+ (100ml/dL)	81ml/L	56.7%
	3+ (200ml/dL)	181ml/L	56.7%
	4+ (300ml/dL)	281ml/L	58.8%

*e. Analytical specificity:*

Interference studies were performed to evaluate the effects of potential interferences commonly found in urine on the performance of URiSCAN 2 ACR strips, using CLSI EP7-A2 as a guide. Testing was done with contrived urine samples at 3 levels of albumin (25, 30, 150 mg/L) and 2 levels of creatinine (50, 300 mg/dL) and different concentrations of the listed compounds with 3 lots of strips in 3 analyzers. Interference is defined as a change in output of  $\geq \pm 1$  color block between spiked and unspiked control sample. The results are summarized in the table below:

Interferences	Highest Concentration tested with no interference mg/dL	
	Albumin	Creatinine
Calcium chloride	190	210
Glycine	420	420
Fructose	70	90
Ascorbic acid	290	310
Citric acid	60	70
Sodium nitrite	7	9
Potassium chloride	1990	1210
Sodium chloride	4900	5100
Sodium bicarbonate	1300	1150
Albumin	N/A	880
Sodium-2-mercaptoethene	520	500
Phenolphthalein	1040	1060
Theophylline	80	85
Riboflavin	10	20
Sodium acetate	240	260
Acetaminophen	35	45
High pH	8	8
Bilirubin	3	4
Hemoglobin	4	5
Blood	290	290
High specific gravity	1.045	1.045
Ketone bodies	300	300
White blood cells	600	600
Glucose	500	500

f. Assay cut-off:

Not applicable.

2. Comparison studies:

a. *Method comparison with predicate device:*

Comparison studies using a total of 351 random fresh urine samples were performed at three different POC sites. Results obtained on the URiSCAN 2 ACR strips and URiSCAN Optima Urine Analyzer and were compared to the Siemens Clinitek Status Analyzer and Clinitek Microalbumin 2 Reagent Strips. Similar performance was obtained at the three sites.

Albumin (n=351)		Predicate device (mg/l)			
		10	30	80	150
URiSCAN Optima (mg/l)	150 (3+)			7	66
	80 (2+)		6	87	1
	30 (1+)		92	1	
	10 (Neg.)	91			
Total		91	98	95	67
Exact agreement (%)		100.0	93.9	91.6	98.5
Within One Block (%)		100.0	100.0	100.0	100.0

Creatinine (n=351)		Predicate device (mg/dl)				
		10	50	100	200	300
URiSCAN Optima (mg/dl)	300 (4+)				2	38
	200 (3+)			1	63	2
	100 (2+)		1	87	1	
	50 (1+)	3	94	2		
	10 (±)	57				
Total		60	95	90	66	40
Exact agreement (%)		95.0	98.9	96.7	95.5	95.0
Within One Block (%)		100.0	100.0	100.0	100.0	100.0

ACR (n=351)		Predicate device (mg/g)		
		<30	30-300	>300
URiSCAN Optima (mg/g)	>300			57
	30-300	2	169	1
	<30	118	4	
Total		120	173	58
Exact agreement (%)		98.3	97.7	98.3
Within One Block (%)		100.0	100.0	100.0

Color:

The URiSCAN Optima also determines the color of the urine automatically. The performance of this function was cleared under k050801. The sponsor stated that there has been no modification to the color function.

*b. Matrix comparison:*

Not applicable. The device is intended for one matrix (urine) only.

3. Clinical studies:

*a. Clinical Sensitivity:*

Not applicable.

*b. Clinical specificity:*

Not applicable.

c. *Other clinical supportive data (when a. and b. are not applicable):*

Not applicable.

4. Clinical cut-off:

Not applicable.

5. Expected values/Reference range:

**Albumin:** Albumin is normally present in urine at concentrations of less than 20 mg/L. Albuminuria is defined as an albumin excretion rate of 30~299 mg/24 hours. Urinary albumin excretions can be temporarily elevated by exercise, urinary tract infections, and acute illness with fever.<sup>2, 3, 4</sup>

**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). Albuminuria 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).<sup>1</sup>

1. Position Statement: Diabetic Nephropathy. Diabetes Care 20: S24-S27; 1997.
2. Burtis, C.A. and Ashwood, E.R.: Tietz Textbook of Clinical Chemistry, 3<sup>rd</sup> ed. Philadelphia: Saunders; 1999; pp. 483-484.
3. Mangili, R. *et al.*: Prevalence of Hypertension and Albuminuria in Adult Type 1 (Insulin Dependent) Diabetic Patients without Renal Failure in Italy – Validation of Screening.
4. American Diabetes Association, Clinical Practice Recommendations, Diabetes Care, Vol. 31, Suppl. 1, January 2008.

**N. Instrument Name:**

URiSCAN Optima Urine Analyzer

**O. System Descriptions:**

1. Modes of Operation:

Single and continuous testing.

2. Software:

FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:

Yes \_\_\_ X \_\_\_ or No \_\_\_\_\_

3. Specimen Identification:

Each sample's identification can be entered prior to testing by way of an alpha-numeric keyboard and optional barcode reader.

4. Specimen Sampling and Handling:

Room temperature urine samples should be measured within 2 hours.

5. Calibration:

The URiSCAN Optima analyzer calibrates automatically before each measurement. The analyzer calibrates by reading the white check bar on each test strip at the appropriate wavelengths to ensure accurate test results. The instrument performs a "self-test" and calibration each time it is turned on. Each time a test is run, the analyzer re-calibrates using a white plastic calibration bar located at the bottom of the analyzer optical system. Reflectance measurements from the bar must match the factory set calibration.

6. Quality Control:

The sponsor recommends the use of commercially available controls intended for monitoring urine strip results at two levels (negative/low and positive).

**P. Other Supportive Instrument Performance Characteristics Data Not Covered In The "Performance Characteristics" Section above:**

Operating conditions of the URiSCAN Optima Urine Analyzer were evaluated and shown to be at a temperature range of 20 °C and 28 °C and relative humidity range between 10% and 70%.

**Q. Proposed Labeling:**

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

**R. Conclusion:**

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.