510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE

A. 510(k) Number:

k150330

B. Purpose for Submission:

New device

C. Measurand:

Urine Creatinine and Albumin

D. Type of Test:

Semi-quantitative colorimetric reagent strip test

E. Applicant:

Acon Laboratories, Inc.

F. Proprietary and Established Names:

Mission Urinalysis Reagent Strips (Microalbumin/Creatinine)

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
JIR	I	21 CFR §862.1645 Urinary protein or albumin (nonquantitative) test system	Chemistry (75)
JFY	II	21 CFR §862.1225 Creatinine test system	Chemistry (75)

H. Intended Use:

1. Intended use(s):

   See indications for use below.

2. Indication(s) for use:

   The Mission Urinalysis Reagent Strips (Microalbumin/Creatinine) are intended for the semi-quantitative measurement of albumin and creatinine in urine samples using the Mission U120 Urine Analyzer. These measurements are used to assist diagnosis for kidney function. It is intended for professional use only at point-of-care locations.

3. Special conditions for use statement(s):

   For prescription use only.

   For point-of-care use.

   Not for visual read.

4. Special instrument requirements:

   Mission U120 Urine Analyzer (k070929)

I. Device Description:

The Mission Urinalysis Reagent Strips (Microalbumin/Creatinine) are plastic strips that contain two reagent pads to test for small amounts of albumin in urine (microalbuminuria), creatinine in urine, and also to determine the albumin-to-creatinine ratio in urine. The strip results are read on the Mission U120 Urine Analyzer (k070929). The product is packaged with a desiccant pack in a plastic bottle.

Composition of the Mission Urinalysis Reagent Strips (Microalbumin/Creatinine):

Key Components	Material/Description
Microalbumin Pad	bis(3′,3′′-diiodo-4′,4′′-dihydroxy-5′,5′′-dinitrophenyl)-3,4,5,6-tetrabromosulfonephthalein; buffer; non-reactive ingredients
Creatinine Pad	copper acetate; diisopropylbenzene dihydroperoxide; 3,3′,5,5′-tetramethylbenzidine; buffer; nonreactive ingredients

J. Substantial Equivalence Information:

1. Predicate device name(s):

   CLINITEK Microalbumin Reagent Strips read on Clinitek Status Analyzer

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

   k972706

3. Comparison with predicate:

Similarities and Differences		
Item	Proposed Device Mission Urinalysis Reagent Strips (Microalbumin/Creatinine)	Predicate Device CLINITEK Microalbumin Reagent Strips (k972706)
Intended Use	For the semi-quantitative measurement of albumin and creatinine in urine samples.	Same
Specimen	Urine	Same
Test time	1 minute	Same
Printed/Displayed Results	Albumin: 10, 30, 80, 150 mg/L Creatinine: 10, 50, 100, 200, 300 mg/dL	Same
Albumin:creatinine ratio Printed/Displayed Results	<30 mg/g (normal) 30-300 mg/g (Abnormal) > 300 mg/g (High Abnormal)	Same
Storage	2 to 30^{o}C	15 to 30^{o}C

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

CLSI EP07-A2, Interference Testing in Clinical Chemistry, Approved Guideline- Second Edition.

L. Test Principle:

The albumin test is based on affinity binding of albumin to a sulfonephthalein dye at a constant pH. The development of pale green to aqua blue indicates the presence of albumin.

The creatinine test is based on the peroxidase-like activity of a copper creatinine complex that catalyzes the reaction of diisopropylbenzene dihydroperoxide and 3,3',5,5'-

tetramethylbenzidine. The resulting color ranges from orange through green to blue.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

To evaluate within run and total precision, three lots of Mission Urinalysis Test Strips (Microalbumin/Creatinine) were used to test urine albumin concentrations of 10, 30, and 150 mg/L and urine creatinine concentrations of 10, 50, and 300 mg/dL. Within-run precision was evaluated at 3 point of care (POC) sites by 3 POC personnel testing each level of the control solution in 20 replicates in one day. Between run precision was evaluated by 3 POC personnel at each of 3 POC sites testing each of the three levels in singlet, 2 runs per day, for 20 days. The samples were blind labeled samples. The exact match block agreement precision study test results are summarized in the tables below:

POC Site 1

Analyte	Concentration	Result (Exact Match/Total)		
		Operator 1	Operator 2	Operator 3
Albumin	10mg/L	14/14	14/14	12/12
	30 mg/L	14/14	14/14	12/12
	150 mg/L	14/14	14/14	12/12
Creatinine	10 mg/dL	14/14	14/14	12/12
	50 mg/dL	14/14	14/14	12/12
	300 mg/dL	14/14	14/14	12/12

POC site 2

Analyte	Concentration	Result (Exact Match/Total)		
		Operator 1	Operator 2	Operator 3
Albumin	10mg/L	14/14	14/14	12/12
	30 mg/L	14/14	14/14	12/12
	150 mg/L	14/14	14/14	12/12
Creatinine	10 mg/dL	14/14	14/14	12/12
	50 mg/dL	14/14	14/14	12/12
	300 mg/dL	14/14	14/14	12/12

POC site 3

Analyte	Concentration	Result (Exact Match/Total)		
		Operator 1	Operator 2	Operator 3
Albumin	10mg/L	14/14	14/14	12/12
	30 mg/L	14/14	14/14	12/12
	150 mg/L	14/14	14/14	12/12
Creatinine	10 mg/dL	13/14	14/14	12/12
	50 mg/dL	14/14	14/14	12/12
	300 mg/dL	14/14	14/14	12/12

The combined precision data for the POC sites is summarized below:

Analyte	Conc.		Total Agreement within same block	Total Agreement within ± 1 block
Albumin	10 mg/L	Within-run	60/60 100%	60/60 100%
		Between run	120/120 100%	120/120 100%
	30 mg/L	Within-run	60/60 100%	60/60 100%
		Between run	120/120 100%	120/120 100%
	150 mg/L	Within-run	60/60 100%	60/60 100%
		Between run	119/120 99.2%	120/120 100%
Creatinine	10 mg/dL	Within-run	60/60 100%	60/60 100%
		Between run	119/120 99.2%	120/120 100%
	50 mg/dL	Within-run	60/60 100%	60/60 100%
		Between run	120/120 100%	120/120 100%
	300 mg/dL	Within-run	60/60 100%	60/60 100%
		Between run	120/120 100%	120/120 100%

b. Linearity/assay reportable range:

This assay reports color block outputs of 10mg/L, 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.

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

Traceability and Expected values: No calibrators or controls are being cleared with this submission.

Stability: Real time and accelerated stability studies were performed for closed vial stability and real time stability study was performed for open vial stability. The study protocol and acceptance criteria was reviewed and found acceptable. Stability data support the following manufacturer's claim: The strip can be stored in 2ºC to 30ºC (35.6 ^{o}F to 30 ^{o}F) in closed package to 24 months, opened package stable for at least 3 months from the manufacture date.

Temperature: Studies were performed to validate the optimal temperature range for testing Mission Urinalysis Reagent Strips (Microalbumin/Creatinine) on the Mission U120 analyzer. The study protocol and acceptance criteria was reviewed and found acceptable. The temperature study data showed that correct Microalbumin/Creatinine results can be obtained by the Mission U120 Urine Analyzer at temperatures between 2ºC and 45ºC.

Humidity: Studies were performed to validate the optimal humidity range for testing Mission Urinalysis Reagent Strips (Microalbumin/Creatinine). The study protocol and acceptance criteria was reviewed and found acceptable. The results demonstrated that the strips were stable up to 50% humidity for over 24 hrs, and at humidity conditions above 60%, the strip was stable for 1 hr.

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 4 levels of albumin and 5 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 by three operators with 3 lots of strips for 3 days generating 81 data points for each level. 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:

		Same block Agreement			
	Conc. Tested	10 mg/L	30 mg/L	80 mg/L	150 mg/L
Albumin	300 mg/L	0%	0%	0%	100% (81/81)
	225 mg/L	0%	0%	0%	100% (81/81)
	150 mg/L	0%	0%	0%	100% (81/81)
	137.5 mg/L	0%	0%	19.8% (16/81)	80.2% (65/81)
	125 mg/L	0%	0%	38.3% (31/81)	61.7% (50/81)
	103.5 mg/L	0%	0%	51.9% (42/81)	48.4% (40/81)
	80 mg/L	0%	0%	100% (81/81)	0%
	60.5 mg/L	0%	12.3% (10/81)	87.7% (71/81)	0%
	55 mg/L	0%	30.9% (25/81)	69.1% (56/81)	0%
	49.5 mg/L	0%	60.5% (49/81)	39.5% (32/81)	0%
	30 mg/L	0%	100% (81/81)	0%	0%
	22 mg/L	13.6% (11/81)	86.4% (70/81)	0%	0%
	20 mg/L	18.5% (15/81)	81.5% (66/81)	0%	0%
	18 mg/L	50.6% (41/81)	49.4% (40/81)	0%	0%
	10 mg/L	100% (81/81)	0%	0%	0%
	7.5 mg/L	100% (81/81)	0%	0%	0%
	5 mg/L	100% (81/81)	0%	0%	0%
	2.5 mg/L	100% (81/81)	0%	0%	0%
	0 mg/L (water)	100% (81/81)	0%	0%	0%

		Same block Agreement				
	Conc. Tested	10 mg/dL	50 mg/dL	100 mg/dL	200 mg/dL	300 mg/dL
Creatinine	600 mg/dL	0%	0%	0%	0%	100% (81/81)
	450 mg/dL	0%	0%	0%	0%	100% (81/81)
	300 mg/dL	0%	0%	0%	0%	100% (81/81)
	275 mg/dL	0%	0%	0%	13.6% (11/81)	86.4% (70/81)
	250 mg/dL	0%	0%	0%	49.4% (40/81)	50.6% (41/81)
	225 mg/dL	0%	0%	0%	81.5% (66/81)	18.5% (15/81)
	200 mg/dL	0%	0%	0%	100% (81/81)	0%
	165 mg/dL	0%	0%	23.5% (19/81)	76.5% (62/81)	0%
	150 mg/dL	0%	0%	44.7% (37/81)	54.3% (44/81)	0%
	135 mg/dL	0%	0%	51.9% (42/81)	48.1% (39/81)	0%
	100 mg/dL	0%	0%	100% (81/81)	0%	0%
	82.5 mg/dL	0%	27.2% (22/81)	72.8% (59/81)	0%	0%
	75 mg/dL	0%	51.9% (42/81)	48.1% (39/81)	0%	0%
	67.5 mg/dL	0%	59.3% (48/81)	40.7% (33/81)	0%	0%
	50 mg/dL	0%	100% (81/81)	0%	0%	0%
	33 mg/dL	18.5% (15/81)	81.5% (66/81)	0%	0%	0%
	30 mg/dL	28.4% (23/81)	71.6% (58/81)	0%	0%	0%
	27.5 mg/dL	55.6% (45/81)	44.4% (36/81)	0%	0%	0%
	10 mg/dL	100% (81/81)	0%	0%	0%	0%

		Same block Agreement				
	Conc. Tested	10 mg/dL	50 mg/dL	100 mg/dL	200 mg/dL	300 mg/dL
	7.5 mg/dL	100% (81/81)	0%	0%	0%	0%
	5 mg/dL	100% (81/81)	0%	0%	0%	0%
	2.5 mg/dL	100% (81/81)	0%	0%	0%	0%
	0 mg/dL (water)	0%	0%	0%	0%	0%

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

Analyte	Color block	Low Concentration cut-off (mg/L)	High Concentration cut-off (mg/L)
Albumin (mg/L)	10	0	18
	30	20	49.5
	80	55	103.5
	150	125	>150
Creatinine (mg/dL)	10	0	27
	50	30	75
	100	82.5	135
	200	150	225
	300	250	>300

e. Analytical specificity:

Interference studies were performed to evaluate the effects of potential interferents commonly found in urine on the performance of Mission Urinalysis Reagent strips, using CLSI EP7-A2 as a guide. Testing was done with contrived urine samples at 3 levels of albumin (10, 30, 150 mg/L) and creatinine (10, 100, 300 mg/dL) and different concentrations of the listed compounds with 3 lots of strips. 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:

Interferent	Conc. Tested	Interference on the Testing Result					
		Result of Albumin			Result of Creatinine		
		10 mg/L	30 mg/L	150 mg/L	10 mg/dL	100 mg/dL	300 mg/dL
Ammonium	100 mg/dL	--*	--	--	--	--	--
Ascorbic acid	200 mg/dL	--	--	--	--	--	--
Bilirubin	170 mg/dL	--	--	--	--	--	--
Calcium chloride	275 mg/dL	--	--	--	--	--	--
Citric acid	75 mg/dL	--	--	--	--	--	--
Creatine	10 mg/dL	--	--	--	--	--	--
Creatinine	600 mg/dL	--	--	--	n/a**	n/a	n/a
Fructose	100 mg/dL	--	--	--	--	--	--
Galactose	80 mg/dL	--	--	--	--	--	--
Glucose	5000 mg/dL	--	--	--	--	--	--
Glycine	450 mg/dL	--	--	--	--	--	--
Hemoglobin	10 mg/dL	+1	+1	--	+1	+1	--
Lactose	10 mg/dL	--	--	--	--	--	--
Lithium	250 mg/dL	--	--	--	--	--	--
Oxalic acid	70 mg/dL	--	--	--	--	--	--
Potassium chloride	1500 mg/dL	--	-2	-2	--	--	--
Riboflavin	10 mg/dL	--	--	--	--	--	--
Sodium acetate	2.25 mg/dL	--	--	--	--	--	--
Sodium bicarbonate	1500 mg/dL	+2	+1	--	--	--	--
Sodium chloride	5500 mg/dL	--	--	--	--	--	--
Sodium nitrate	10 mg/dL	--	--	--	--	--	--
Sodium nitrite	10 mg/dL	--	--	--	--	--	--
Sodium phosphate	500 mg/dL	--	--	--	--	--	--
Theophylline	100 mg/dL	--	--	--	--	--	--
Urea	400 mg/dL	--	--	--	--	--	--
Uric acid	150 mg/dL	--	--	--	--	--	--
Blood	0.05%	+2	+1	--	+1	+1	--
Leucocyte	2500 leu/μL	--	--	--	--	--	--
Human IgG	25 mg/dL	+1	+1	--	--	--	--

*-- indicates that the no interference was observed at these interferent and analyte levels.

**n/a: creatinine was not tested as an interfering substance for the creatinine test pad

Specific Gravity and pH:

To test the effects of specific gravity, 5 fresh urine samples were pooled and separated into 9 aliquots with approximate specific gravities of 1.000, 1.005, 1.010, 1.015, 1.020, 1.025, 1.030, 1.035 and 1.040. The samples were spiked or diluted to achieve the desired albumin (10, 80, and 150 mg/L) and creatinine (10, 100, 300 mg/dL) concentrations. Interference was defined by the sponsor as results being ≥ 1 block outside the expected color block. The results showed that urine specific gravity range of 1.005 to 1.040 does not affect the results of the albumin test, but specific gravity at 1.000 will generate a false low result on the albumin test. Specific gravity from 1.000 to 1.030 will not affect the results of creatinine test; however specific gravity higher than or equal to 1.035 will generate a false high result on the creatinine test.

To test the effects of pH, 5 fresh urine samples were pooled and separated into 7 aliquots. The pH of the aliquots was adjusted to a range of 4.00 to 10.00 in 1 pH unit increments and were spiked or diluted with albumin and creatinine, respectively. Interference was defined by the sponsor as results being ≥ 1 block outside the expected color block. Samples were tested in replicates of 5, using three lots of each format of the devices, and results showed that urine pH range of 4.00 to 9.00 does not affect the results of the albumin test but samples at pH 10.0 would generate false high results. Urine sample pH from 4 to 10 did not affect the creatinine test results.

The sponsor includes the following in the labeling regarding potentially interfering substances:

Results of the substances at the indicated concentration were found to interfere with the albumin and/or creatinine test are summarized in the table below:

Substances	Conc. Tested	Interference on the Albumin Result	Interference on the Creatinine Result
Human IgG	25 mg/dL	+1 Block	N/A
Sodium Bicarbonate	1500 mg/dL	+1 to +2 Blocks	N/A
Potassium Chloride	1500 mg/dL	-2 Blocks	N/A
Hemoglobin	10 mg/dL	+1 to +2 Blocks	+1 Block
Blood	0.05%	+1 Block	+1 Block

The Urinalysis Reagent Strips (Urine) may be affected by substances that cause abnormal urine color such as drugs containing azo dyes (e.g. Pyridium, Azo Gantrisin, Azo Gantanol), nitrofurantoin (Microdantin, Furadantin), and riboflavin. Urine specimen contaminated with soaps, detergents, antiseptics, or skin cleansers may also affect test results.

For albumin, a pH ≥10.0 or a specific gravity of 1.000 will affect albumin test results; whereas, a specific gravity ≥1.035 will generate falsely elevated results for creatinine.

Sample Carryover study:

The sponsor performed a carryover study to evaluate the interference of the reagent pad to each other on the Microalbumin/Creatinine reagent strip when read by the Mission U120 analyzer. Three concentration of albumin (10, 30, and 150 mg/L) and creatinine (10, 50, and 300 mg/dL) were tested. The reagent strip was dipped into the urine sample and removed. The strip was held vertically to allow excess liquid from the microalbumin pad to run onto the creatinine pad before blotting and testing on the analyzer. The process was repeated to allow excess liquid from the creatinine pad to run onto the Microalbumin pad before blotting and testing on the analyzer. Interference was defined by the sponsor as results being outside the expected color block. Each urine concentration was tested in replicates of 5. The results of the study demonstrated no interference between the reagent pads was observed when liquid form one reagent pad is carried over to another reagent pad and tested on the Mission U120 analyzer.

Dipping/wetting time study:

The sponsor performed a study to evaluate the effect of different dipping and wetting times of the Microalbumin/Creatinine reagent strip in urine on the Mission U120 Analyzer albumin and creatinine result reading. Three concentration of albumin (10, 30, and 150 mg/L) and creatinine (10, 50, and 300 mg/dL) were tested. The strips were dipped into the urine samples and allowed to remain in the urine for 2s, 5s and 10s. Then, the strips were removed from the urine sample but allowed to remain wet (not blotted) for 0 s, 15s, 30s, 60s, 90s, 2min, 3 min, 5 min, and 10 min before placing the strip on the analyzer for testing. Testing was performed for each time point in replicates of 5. Interference was defined by the sponsor as results being ≥ 1 block outside the expected color block. Data from the study showed that to generate the correct testing results, the optimum ranges of strip dipping time and strip wetting time for Microalbumin/Creatinine strips are listed below:

Reagent	Range of strip dipping time	Range of strip wetting time
Microalbumin	0-10s	0s-10 min
Creatinine	0-10s	0s-1 min

f. Assay cut-off:

See detection limits (M. 1. d.) above.

2. Comparison studies:

a. Method comparison with predicate device:

Method comparison studies were performed to evaluate the accuracy of the Mission Urinalysis Microalbumin/Creatinine Reagent Strips read by the Mission U120 Urine Analyzer compared to the predicate, the Clinitek Microalbumin Reagent Strips read by the Clinitek Status Analyzer. Testing was performed at 3 point-of-care (POC) sites by 9 operators (3 per site). One hundred and twenty total urine samples were randomly collected from patients at each of the 3 POC sites for a total of 360 native samples. An additional ten samples at each site (8% of the total number of samples tested) were contrived to cover the entire measuring range, for an overall total of 390 samples. Each intended user tested approximately the same number of samples at each site. Three lots of strips were used for the study.

The method comparison data for urine albumin and creatinine testing for each of the 3 sites are shown in the tables below:

Albumin (Site 1, n= 130)		Predicate Device			
		10 mg/L	30 mg/L	80 mg/L	150 mg/L
Mission Urinalysis Reagent Strips	10 mg/L	61	3	0	0
	30 mg/L	6	24	3	0
	80 mg/L	0	2	11	2
	150 mg/L	0	0	0	18
Total		67	29	14	20
Agreement at same block		91.0%	82.8%	78.6%	90.0%
Agreement within ±1 block		100%	100%	100%	100%

Albumin (Site 2, n= 130)		Predicate Device			
		10 mg/L	30 mg/L	80 mg/L	150 mg/L
Mission Urinalysis Reagent Strips	10 mg/L	17	3	0	0
	30 mg/L	4	17	5	0
	80 mg/L	0	2	18	9
	150 mg/L	0	0	1	54
Total		21	22	24	63
Agreement at same block		81.0%	77.3%	75.0%	81.5%
Agreement within ± 1 block		100%	100%	100%	100%

Albumin (Site 3, n= 130)		Predicate Device			
		10 mg/L	30 mg/L	80 mg/L	150 mg/L
Mission Urinalysis Reagent Strips	10 mg/L	42	3	0	0
	30 mg/L	10	30	4	0
	80 mg/L	0	4	21	2
	150 mg/L	0	0	1	13
Total		52	37	26	15
Agreement at same block		80.8%	81.1%	80.8%	86.7%
Agreement within ± 1 block		100%	100%	100%	100%

Creatinine (Site 1, n= 130)		Predicate Device				
		10	50	100	200	300
Mission Urinalysis Reagent Strips	10	10	2	0	0	0
	50	0	29	4	0	0
	100	0	6	29	4	0
	200	0	0	6	26	1
	300	0	0	0	1	12
Total		10	37	39	31	13
Agreement at same block		100%	82.7%	74.4%	83.9%	92.3%
Agreement within ±1 block		100%	100%	100%	100%	100%

Creatinine (Site 2, n= 130)		Predicate Device				
		10	50	100	200	300
Mission Urinalysis Reagent Strips	10	15	3	0	0	0
	50	1	39	3	0	0
	100	0	3	26	4	0
	200	0	0	4	22	1
	300	0	0	0	1	8
Total		16	45	33	27	9
Agreement at same block		93.8%	86.7%	78.8%	81.5%	88.9%
Agreement within ±1 block		100%	100%	100%	100%	100%

Creatinine (Site 3, n= 130)		Predicate Device				
		10	50	100	200	300
Mission Urinalysis Reagent Strips	10	10	4	0	0	0
	50	3	36	5	0	0
	100	0	4	32	4	0
	200	0	0	2	20	0
	300	0	0	0	0	10
Total		13	44	39	24	10
Agreement at same block		76.9%	81.8%	82.1%	83.3%	100%
Agreement within ±1 block		100%	100%	100%	100%	100%

For all three sites combined:

Albumin		Predicate Device			
		10 mg/L	30 mg/L	80 mg/L	150 mg/L
Mission Urinalysis Reagent Strips	10 mg/L	120	9	0	0
	30 mg/L	20	71	12	0
	80 mg/L	0	8	50	13
	150 mg/L	0	0	2	85
Total		140	88	64	98
Agreement at same block		85.7%	80.7%	78.1%	86.7%
Agreement within ± 1 block		100%	100%	100%	100%

Creatinine		Predicate Device				
		10 mg/dL	50 mg/dL	100 mg/dL	200 mg/dL	300 mg/dL
Mission Urinalysis Reagent Strips	10 mg/dL	35	9	0	0	0
	50 mg/dL	4	104	12	0	0
	100 mg/dL	0	13	87	12	0
	200 mg/dL	0	0	12	68	2
	300 mg/dL	0	0	0	2	30
Total		39	126	111	82	32
Agreement at same block		89.7%	82.5%	78.4%	82.9%	98.3%
Agreement within ± 1 block		100%	100%	100%	100%	100%

Albumin to creatinine ratio percent agreement for all three sites combined:

Albumin:Creatinine Ratio (n=390)	Predicate Device		
Mission Urinalysis (Microalbumin/Creatinine) Reagent Strips	<30 mg/g	30-300 mg/g	>300 mg/g
<30 mg/g	164	12	0
30-300 mg/g	15	112	11
>300 mg/g	0	4	72
Total	179	128	83
Agreement at same block	91.6%	87.5%	86.7%
Agreement within ± 1 block	100%	100%	100%

The agreement of albumin to creatinine ratios of positive and negatives at cutoff of <30 mg/g were 94.3% and 91.6% respectively. Of the 211 positive results, 5.7%

(12/211) were negative. Of the 179 assays, albumin to creatinine ratio negative results, 8.4% (15/179) were positive. In summary, the overall exact agreement between Mission Urinalysis Strips (Microalbumin/Creatinine) and the predicate for positive albumin results was 89.2%, and the overall agreement for ±1 block was 100%.

b. Matrix comparison:

Not applicable

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:

The expected values are included in the labeling and are taken from literature references.

Normally, albumin is present in urine at concentrations < 20 mg/L[1]. Results of 20-200 mg/L may indicate microalbuminuria. It is associated with early-stage kidney disease when a small amount of albumin, also called microalbumin, is consistently present in urine. Clinical albuminuria is indicated by results of > 200 mg/L. These levels can be predictive of albumin excretion rates of 30-300 mg/24 hours and >300 mg/24 hours, respectively[2-3]. Exercise, acute illness and fever, and urinary tract infections may temporarily elevate urinary albumin excretions. Creatinine concentrations of 10-300 mg/dL are normally present in urine.

Albumin is normally present in urine at concentrations of <30 mg albumin/g creatinine. Microalbuminuria is indicated at a ratio result of 30-300 mg/g (abnormal) and clinical albuminuria at a ratio of >300 mg/g (high abnormal)[4].

1. Burtis, C.A. and Ashwood, E.R.: Tietz Textbook of Clinical Chemistry, 3rd ed. Philadelphia: Saunders; 1999; pp. 483-484.
2. Mangili, R. et al.: Prevalence of Hypertension and Microalbuminuria in Adult Type 1

(Insulin-Dependent) Diabetic patients Without Renal Failure in Italy-Validation of Screening Techniques to Detect Microalbuminuria. Acta Diabetol. 29: 156-166; 1992.
3. American Diabetes Association, Clinical Practice Recommendations, Diabetes Care, Vol. 31, Suppl. 1, January 2008
4. Position Statement: Diabetic Nephropathy. Diabetes Care 20: S24-S27; 1997.

N. Proposed Labeling:

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

O. Conclusion:

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