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

A. 510(k) Number:

k052719

B. Purpose for Submission:

Clearance to market URITEST 10 Urinalysis Reagent Strips for urinalysis

C. Measurand:

Urobilinogen, bilirubin and its conjugates, ketones (acetoacetic acid), blood, glucose, protein, nitrite, leukocytes, glucose, specific gravity, and pH, in urine

D. Type of Test:

Qualitative and semi-quantitative urine tests

E. Applicant:

ARJ Medical Inc.

F. Proprietary and Established Names:

URITEST Urinalysis Reagent Strips

G. Regulatory Information:

1. Regulation section:
   21 CFR §864.6550: Occult blood test.
   21 CFR §862.1340: Urinary glucose (nonquantitative) test system.
   21 CFR §862.1785: Urinary urobilinogen (nonquantitative) test system.
   21 CFR §862.1115: Urinary bilirubin and its conjugates (nonquantitative) test system.
   21 CFR §862.1435: Ketones (nonquantitative) test system.
   21 CFR §862.1645: Urinary protein or albumin (nonquantitative) test system.
   21 CFR §862.1510: Nitrite (nonquantitative) test system.
   21 CFR §864.7675: Leukocyte peroxidase test.
   21 CFR §862.1550: Urinary pH (nonquantitative) test system.

2. Classification:

Class II: Urinary Glucose and Occult Blood

Class I: Urinary Leukocytes, Urinary pH, Nitrite, Urinary Protein, Ketones, Urinary Urobilinogen, Urinary Bilirubin

3. Product code:

   Occult blood test - JIO
   Urinary glucose (nonquantitative) test system - JIL
   Urinary urobilinogen (nonquantitative) test system - CDM
   Urinary bilirubin and its conjugates (nonquantitative) test system - JJB
   Ketones (non-quantitative) test system - JIN
   Urinary protein or albumin (non-quantitative) test system - JIR
   Nitrite (non-quantitative) test system - JMT
   Leukocyte peroxidase test - LJX
   Urinary pH (nonquantitative) - CEN

4. Panel:
   Chemistry (75)
   Hematology (82)

H. Intended Use:

1. Intended use(s):
   See indications for use below.

2. Indication(s) for use:
   URITEST 10 Urinalysis Reagent Strips provide qualitative and semi-quantitative tests for glucose, bilirubin, ketones (acetoacetic acid), specific gravity, blood, pH, protein, urobilinogen, nitrites, and leukocytes in urine. Test results may provide information regarding the status of carbohydrate metabolism, kidney and liver function, acid-base balance, and bacteriuria.

   ARJ Medical URITEST 10 Urinalysis Reagent Strips are for single use in professional near patient (point-of-care) facilities and centralized laboratory locations by medical technologists both read visually and on the Bayer Family of Clinitek Analyzers. The strips are intended for use in screening at-risk patients to assist diagnosis in the following areas:

   Kidney Function
   Urinary Tract infections
   Carbohydrate metabolism
   Liver Function
   Acid-Base balance
   Urine Concentration

3. Special conditions for use statement(s):

   For prescription use only

4. Special instrument requirements:

   Bayer Clinitek 50, 100, 200, 500 Analyzers and visual readings.

I. Device Description:

URITEST 10 Urinalysis Reagent Strips provide qualitative and semi-quantitative for pH, specific gravity, ketones, blood, protein, nitrite, leukocytes, glucose, bilirubin, and urobilinogen in urine. URITEST 10 Urinalysis Reagent Strips are firm plastic, dry reagent strips. The reagent areas are dipped into the urine sample and read visually according to a color chart or are read instrumentally with a Bayer® Family of Clinitek Urine Analyzers. The results are available within 120 seconds. To obtain optimal results, it is necessary to use fresh, well-mixed and uncentrifuged urine.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Bayer Corporation MULTISTIX 10 SG Regent Strip

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

   k852611

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Specimen	Urine	Same
Intended Use Audience	Patients of physicians, hospitals, and clinics	Same
Test Principles	Ingredients that change color in reaction with Analytes	Same
Output values	Negative and 2 to 6 positive values	Same

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

CLSI EP6-A: “Evaluation of Linearity of Quantitative Measurement Procedures: A Statistical Approach”; Approved Guideline, 2003

CLSI EP09-A2: “Method Comparison and Bias Estimation Using Patient Samples”; Approved Guideline, 2002

CLSI EP10-A2: “Preliminary Evaluation of Quantitative Clinical Laboratory Methods”

CLSI EP12-A: “User Protocol for Evaluation of Qualitative Test Performance”; Approved Guideline, 2002

L. Test Principle:

The device is composed of multiple chemically reactive spots separate from each other on a plastic strip. Read-out is accomplished by visually matching the position and color of an exposed spot to a color coded chart provided with the device.

For the detection of urobilinogen, the device employs a modified Ehrlich’s reaction. Urobilinogen reacts with Ehrlich’s reagent to form a red-colored compound. Color changes from light orange-pink to dark pink.

For the detection of glucose, the device employs glucose oxidase to catalyze the oxidation of glucose to form hydrogen peroxide. The hydrogen peroxide thus formed then oxidizes a chromogen on the reaction pad by the action of peroxidase.

For the detection of bilirubin, bilirubin reacts with a dichlorobenzene diazonium salt in acid media to produce a colored product vie an azo coupling. Bilirubin concentration is proportional to the intensity or the resulting purple color.

The device uses Legal’s test-nitroprusside reaction for the detection of ketones. Acetoacetic acid in an alkaline medium reacts with nitroferricyanide to produce a color change from beige to purple

The device uses a correlation between the concentration of ionic species and the sample’s specific gravity to report an estimated specific gravity. Electrolyte (M+ X-) in the form of salt in urine reacts with poly-methyl vinyl ether and maleic acid which is a weak acid ionic exchanger. The reaction produces hydrogen ions which react with a pH indicator that causes a color change.

To detect blood, the device exploits the pseudo-peroxidase activity of the haem moiety of hemoglobin and myoglobin. A chromogen is oxidized by a hydroperoxide in the presence of haem and produces a green color.

To qualitatively estimate protein concentration, the device uses the “error of indicators” principle. Proteins interact with an ionizable electrolyte driving the release of protons which in turn interact with a spectator indicator. The color change in the indicator is correlated with the protein concentration.

The device detects nitrite through a reaction with an aromatic amino sulphanilamide

to form a diazonium compound. The diazonium compound reacting with tetrahydro benzo(h)quinolin-3-phenol causes the color change.

One location on the strip contains an indoxyl ester and diazonium salt. Leukocytes contain an esterase that hydrolyzes the indoxyl ester. The liberated compound reacts with the diazonium salt on the strip to generate a purple compound. The concentration of leukocytes is correlated with the production of a purple color.

The device used two indicators to measure pH in a broad range of urinary pHs.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

The company demonstrated the precision of their device using 2 levels of commercial urine control. The company referenced CLSI EP10-A2 "Preliminary Evaluation of Quantitative Clinical Laboratory Methods" in determining the precision of their device. The company made 10 measurements per concentration level two times a day for 10 days for each of 3 lots of strips. Strips were read using a Clinitek 100 Urine Analyzer.

For the Level I material, the company found:

Analyte	Reading	% Strips at Reading
Urobilinogen	3.2	100
Bilirubin	Negative	100
Ketone	Negative	100
Blood	Negative	100
Protein	Negative	100
Nitrite	Negative	100
Leukocyte	Negative	100
Glucose	Negative	100
Specific Gravity	1.02	100
pH	7.0	100

For the Level II material, the company found:

Analyte	Reading	% Strips at Reading

Urobilinogen	66	100
Bilirubin	Moderate	100
Ketone	1.5	100
Blood	200	100
Protein	3.0	100
Nitrite	+	100
Leukocyte	125	100
Glucose	28	100
Specific Gravity	1.02	100
pH	7.0	100

b. Linearity/assay reportable range:

The company validated their claims for the concentration divisions by testing pooled, negative urine spiked to specific target concentrations. Each concentration of analyte was tested 20 times for across 3 lots of strips for a total of 60 measurements at each concentration. The company used 1 Clinitek 100 to perform these measurements.

For Urobilinogen, the company challenged their device using samples spiked to 0.2, 0.8, and 1.0 mg/dL urobilinogen. The company found:

[Urobilinogen], mg/dL	Number of strips reading at: 0.2 mg/dL	Number of strips reading at: 1 mg/dL	Number of strips reading at: 2 mg/dL	% Positive
0.2 mg/dL	58	2	0	0.7%
0.8 mg/dL	28	32	0	53.3%
1.0 mg/dL	1	59	0	98.3%

For bilirubin, the company challenged their device using samples spiked to 0.2, 0.3, and 0.5 mg/dL bilirubin. The company found:

[bilirubin], mg/dL	Number of strips reading at: Negative	Number of strips reading at: "S"	Number of strips reading at: "M"	Number of strips reading at: "L"	% Positive
0 mg/dL	59	1	0	0	0.3%

0.2 mg/mL	45	15	0	0	25.0%
0.3 mg/dL	27	33	0	0	55.0%
0.5 mg/dL	5	55	0	0	91.7%

For ketones, the company challenged their device with 5, 10, and 15 md/dL acetoacetate. The company found:

[ketones], mg/dL	Number of strips reading at: Negative	Number of strips reading at: 5 mg/dL	Number of strips reading at: 15 mg/dL	Number of strips reading at: 40 mg/dL	% Positive
0 mg/dL	60	0	0	0	0.0%
5 mg/dL	14	46	0	0	76.7%
10 mg/dL	1	24	35	0	98.3%
15 mg/dL	0	3	49	8	100.0%

For blood, the company challenged their device with specimens adjusted to 5, 10, 15, 20 Cells/µL. A sample at 400 Cells/µL was diluted with negative, pooled urine. Cell counts were confirmed by microscopic examination. The company found:

# RBC/µL	Number of strips reading at: Negative	Number of strips reading at: 10 mg/dL	Number of strips reading at: 25 mg/dL	Number of strips reading at: 80 mg/dL	% Positive
0 RBC/µL	59	1	0	0	1.7%
5 RBC/µL	34	25	1	0	42.9%
10 RBC/µL	20	32	8	0	66.7%
15 RBC/µL	8	19	33	0	87.1%
20 RBC/µL	0	3	57	0	100%

For protein, the company challenged their device with urine containing 0.12, 0.15, 0.24, and 0.3 g/L protein. Samples were created by spiking human

albumin into pooled urine negative to protein. Final concentrations were determined by use of a commercial total protein kit. The company found:

[protein], mg/dL	Number of strips reading at: Negative	Number of strips reading at: Trace	Number of strips reading at: 30 mg/dL	Number of strips reading at: 100 mg/dL	% Positive
0 mg/dL	59	1	0	0	1.7%
12 mg/dL	58	2	0	0	3.3%
15 mg/dL	31	28	1	0	48.3%
24 mg/dL	17	33	10	0	71.7%
30 mg/dL	0	2	49	9	100%

For nitrite, the company challenged their device with urine spiked to 0.08, 0.10, and 0.12 mg/dL. Nitrite concentrations were independently determined by a reference lab. The company found:

[Nitrite], mg/dL	Number of strips reading at: Negative	Number of strips reading at: Positive	% Positive
0.0 mg/dL	59	1	1.7%
0.08 mg/dL	43	17	28.3%
0.1 mg/dL	25	35	58.3%
0.12 mg/dL	5	55	91.7%

For leukocytes, the company challenged their device with sampled prepared with urine diluted from high cell count sample. Leukocytes counts were determined by microscopy. The company found:

# Leukocytes/μL	Number of strips reading at: Negative	Number of strips reading at: 15 /μL	Number of strips reading at: 70 /μL	Number of strips reading at: 125 /μL	Number of strips reading at: 500 /μL	% Positive
0 Leukocytes /μL	59	1	0	0	0	1.7%
5 Leukocytes /μL	41	19	0	0	0	31.7%
15 Leukocytes /μL	10	46	4	0	0	83.3%
25 Leukocytes /μL	1	11	39	9	0	98.3%

For glucose, the company challenged their device with samples spiked to 50, 72, and 100 mg/dL. Glucose concentrations were independently determined using a commercial test kit. The company found:

[Glucose], mg/dL	Number of strips reading at: Negative	Number of strips reading at: 100 mg/dL	Number of strips reading at: 250 mg/dL	Number of strips reading at: 500 mg/dL	Number of strips reading at: 1000 mg/dL	% Positive
0 mg/dL	60	0	0	0	0	0.0%
50 mg/dL	43	17	0	0	0	28.3%
72 mg/dL	21	38	1	0	0	65.0%
100 mg/dL	3	54	3	0	0	95.0%

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

The company assessed the stability of their proposed device using real-time aging studies. Different lots of manufactured strips were stored at both 2-8 °C and 25 °C for 18 months. Data provided by the company demonstrated that the performance of the aged device was comparable to that of newly manufactured strips.

The data provided by the company supports their claim for an 18 month shelf life when stored as indicated on the product insert.

d. Detection limit:

To substantiate their claims for a lower limit of detection, the company challenged their device with samples prepared at 80% and 120% of the lowest reported concentration. The company used 20 strips from each of 3 lots for a total of 60 measurements at each concentration, 180 measurements for each analyte. Samples were prepared and concentrations confirmed as in Section b) above.

For glucose, the company showed:

Sample	0.8*Cutoff	Cutoff	1.2*Cutoff
Negative	58	0	0
Positive	2	60	60
% Correct	96.7%	100%	100%
Cutoff Used:	50 mg/dL		

For bilirubin, the company showed:

Sample	0.8*Cutoff	Cutoff	1.2*Cutoff
Negative	56	1	0
Positive	4	59	60
% Correct	93.3%	98.3%	100%
Cutoff Used:	0.5 mg/dL		

For ketones, the company showed:

Sample	0.8*Cutoff	Cutoff	1.2*Cutoff
Negative	58	0	0
Positive	2	60	60
% Correct	96.7%	100%	100%
Cutoff Used:	5 mg/dL		

For blood, the company showed:

Sample	0.8*Cutoff	Cutoff	1.2*Cutoff
Negative	55	0	0
Positive	5	60	60
% Correct	91.7%	100%	100%
Cutoff Used:	10 RBC/μL		

For protein, the company showed:

Sample	0.8*Cutoff	Cutoff	1.2*Cutoff
Negative	56	2	0

Positive	4	58	60
% Correct	93.3%	96.7%	100%
Cutoff Used:	12 mg/dL		

For urobilinogen, the company showed:

Sample	0.8*Cutoff	Cutoff	1.2*Cutoff
Negative	56	1	0
Positive	4	59	60
% Correct	93.3%	98.3%	100%
Cutoff Used:	2 mg/dL		

For nitrites, the company showed:

Sample	0.8*Cutoff	Cutoff	1.2*Cutoff
Negative	59	0	0
Positive	1	60	60
% Correct	98.3%	100%	100%
Cutoff Used:	0.05 mg/dL		

For leukocytes, the company showed:

Sample	0.8*Cutoff	Cutoff	1.2*Cutoff
Negative	54	4	0
Positive	6	56	60
% Correct	93.3%	90.0%	100%
Cutoff Used:	25 WBC/μL		

e. Analytical specificity:

The company tested a variety of endogenous and exogenous compounds in negative and positive urine samples. Fresh negative urine was spiked with the analyte of interest and the interfering analyte. The company found that the following analytes and concentrations did not impact the results of their device:

Compound Tested	Concentration Used
Albumin	800 mg/dL
Citric Acid	50 mg/dL
Bilirubin	3.0 mg/dL
Creatine	8 mg/dL
Acetoacetate acid	1 mM
Ammonium Chloride	189 mg/dL

Compound Tested	Concentration Used
Calcium Chloride	50 mg/dL
Creatinine	800 mg/dL
Glycine	1000 mg/dL
KCl	550 mg/dL
Oxalic Acid	70 mg/dL
Sodium Bicarbonate	1500 mg/dL
Sodium Nitrate	0.26 mg/dL
Sodium Nitrite	0.3 mg/dL
Sodium Phosphate	16 mg/dL
Urea	3000 mg/dL
Riboflavin	100 mg/L
Theophylline	100 mg/L
Phenolphthalein	1200 mg/L

The company did find that high levels of ketones (> 10 mg/dL) and ascorbic acid (>8.8 mg/dL) would interfere with the measurements of glucose in urine using this device. The company noted this interference in their product literature.

The company also noted that ascorbic acid at concentrations of 8.8 mg/dL or higher interfered with the device's detection of blood. The company noted this interference in their product literature.

f. Assay cut-off:

Not applicable in this submission.

2. Comparison studies:

a. Method comparison with predicate device:

The company substantiated their claim for equivalence by direct comparison using clinical samples in four hospitals. The company compared the performance of their device to their predicate using visual comparison and on 4 different models of Clinitek analyzers. Each sample was measured in duplicate for a total of 10 measurements across the 5 platforms, i.e. visual reading by eight users and 4 analyzers, for a total of 1514 measurements. The company made measurements over 3 different manufacturing lots of the proposed device.

For glucose, the company determined:

Reagent: Glucose
Instrument: Clinitek 50

Proposed Device	**1000**	0	0	0	2	162
	500	0	0	3	112	3
	250	1	2	138	1	0
	100	2	171	0	0	0
	Neg	903	14	0	0	0
	Glucose	**Neg**	**100**	**250**	**500**	**1000**
		Predicate Device				

Reagent: Glucose
Instrument: Clinitek 100

Proposed Device	**1000**	0	0	0	2	165
	500	0	0	3	108	4
	250	0	6	141	0	0
	100	4	168	0	0	0
	Neg	901	12	0	0	0
	Glucose	**Neg**	**100**	**250**	**500**	**1000**
		Predicate Device				

Reagent: Glucose
Instrument: Clinitek 200

Proposed Device	**1000**	0	0	0	2	168
	500	0	0	4	106	7
	250	0	9	142	2	0
	100	5	161	0	0	0
	Neg	898	10	0	0	0
	Glucose	**Neg**	**100**	**250**	**500**	**1000**
		Predicate Device				

Reagent: Glucose
Instrument: Clinitek 500

Proposed Device	**1000**	0	0	0	2	168
	500	0	0	2	114	3
	250	0	7	139	0	0
	100	2	167	1	0	0
	Neg	899	10	0	0	0
	Glucose	**Neg**	**100**	**250**	**500**	**1000**
		Predicate Device				

Reagent: Glucose
Instrument: Visual

Proposed Device	**≥ 2000**	0	0	0	0	12	89
	1000	0	0	0	6	54	0
	500	0	0	2	123	11	0
	250	0	5	163	2	0	0
	100	2	153	3	0	0	0
	Neg	886	3	0	0	0	0
	Glucose	**Neg**	**100**	**250**	**500**	**1000**	**≥ 2000**
		Predicate Device					

For blood, the company determined:

Reagent: Blood
Instrument: Clinitek 50

Proposed Device	**200**	0	0	0	8	191
	80	0	0	12	99	5
	25	0	9	100	5	0
	Trace	8	122	3	0	0
	Neg	944	8	0	0	0
	Blood	**Neg**	**Trace**	**25**	**80**	**200**
		Predicate Device				

Reagent: Blood
Instrument: Clinitek 100

Proposed Device	**200**	0	0	0	4	203
	80	0	0	4	111	6
	25	0	3	110	4	0
	Trace	11	118	3	0	0
	Neg	924	8	0	0	0
	Blood	**Neg**	**Trace**	**25**	**80**	**200**
		Predicate Device				

Reagent: Blood
Instrument: Clinitek 200

Proposed Device	**200**	0	0	0	4	183
	80	0	0	2	117	6
	25	0	3	110	3	0
	Trace	10	125	5	0	0
	Neg	937	9	0	0	0
	Blood	**Neg**	**Trace**	**25**	**80**	**200**
		Predicate Device				

Reagent: Blood
Instrument: Clinitek 500

Proposed Device	**200**	0	0	0	6	185
	80	0	0	3	114	7
	25	0	2	105	3	0
	Trace	8	124	5	0	0
	Neg	941	11	0	0	0
	Blood	**Neg**	**Trace**	**25**	**80**	**200**
		Predicate Device				

Reagent: Blood
Instrument: Visual

Proposed Device	**200**	0	0	0	6	183
	80	0	0	6	109	7
	25	0	5	103	10	0
	Trace	6	122	3	0	0
	Neg	941	13	0	0	0
	Blood	**Neg**	**Trace**	**25**	**80**	**200**
		Predicate Device				

For leucocytes, the company determined:

Reagent: Leucocytes
Instrument: Clinitek 50

Proposed Device	**Large**	0	0	0	1	136
	Mod	0	0	2	116	2
	Small	0	1	196	3	0
	Trace	2	153	5	0	0
	Neg	893	4	0	0	0
	Leukocytes	**Neg**	**Trace**	**Small**	**Mod**	**Large**
		Predicate Device				

Reagent: Leucocytes
Instrument: Clinitek 100

Proposed Device	**Large**	0	0	0	1	134
	Mod	0	0	2	118	6
	Small	0	1	196	3	0
	Trace	3	152	1	0	0
	Neg	894	2	0	0	0
	Leukocytes	**Neg**	**Trace**	**Small**	**Mod**	**Large**
		Predicate Device				

Reagent: Leucocytes
Instrument: Clinitek 200

Proposed Device	**Large**	0	0	0	1	137
	Mod	0	0	3	121	0
	Small	0	1	197	2	0
	Trace	2	156	0	0	0
	Neg	893	1	0	0	0
	Leukocytes	**Neg**	**Trace**	**Small**	**Mod**	**Large**
		Predicate Device				

Reagent: Leucocytes
Instrument: Clinitek 500

Proposed Device	Large	0	0	0	3	115
	Mod	0	0	6	124	4
	Small	0	4	197	6	0
	Trace	2	156	0	0	0
	Neg	891	6	0	0	0
	Leukocytes	Neg	Trace	Small	Mod	Large
		Predicate Device				

Reagent: Leucocytes
Instrument: Visual

Proposed Device	Large	0	0	0	1	119
	Mod	0	0	3	122	3
	Small	0	3	204	5	0
	Trace	2	155	1	0	0
	Neg	893	3	0	0	0
	Leukocytes	Neg	Trace	Small	Mod	Large
		Predicate Device				

For nitrite, the company determined:

Reagent: Nitrite
Instrument: Clinitek 50

Proposed Device	Pos	0	594
	Neg	915	5
	Nitrite	Neg	Pos
		Predicate Device	

Reagent: Nitrite
Instrument: Clinitek 100

Proposed Device	Pos	18	569
	Neg	918	9
	Nitrite	Neg	Pos
		Predicate Device	

Reagent: Nitrite
Instrument: Clinitek 200

Proposed Device	Pos	6	582
	Neg	926	0
	Nitrite	Neg	Pos
		Predicate Device	

Reagent: Nitrite
Instrument: Clinitek 500

Proposed Device	Pos	0	594
	Neg	915	5
	Nitrite	Neg	Pos
		Predicate Device	

Reagent: Nitrite
Instrument: Visual

Proposed Device	**Pos**	18	569
	Neg	918	9
	Nitrite	**Neg**	**Pos**
		Predicate Device	

For proteins, the company determined:

Reagent: Protein
Instrument: Clinitek 50

Proposed Device	**300**	0	0	00	9	162
	100	0	0	3	113	1
	30	0	2	134	0	0
	Trace	0	174	2	0	0
	Neg	907	7	0	0	0
	Protein	**Neg**	**Trace**	**30**	**100**	**300**
		Predicate Device				

Reagent: Protein
Instrument: Clinitek 100

Proposed Device	**300**	0	0	0	10	169
	100	0	0	3	111	0
	30	0	3	144	1	0
	Trace	0	173	5	0	0
	Neg	890	9	0	0	
	Protein	**Neg**	**Trace**	**30**	**100**	**300**
		Predicate Device				

Reagent: Protein
Instrument: Clinitek 200

Proposed Device	300	0	0	0	2	157
	100	0	0	3	109	2
	30	0	3	135	1	0
	Trace	0	183	4	0	0
	Neg	902	13	0	0	0
	Protein	Neg	Trace	30	100	300
		Predicate Device				

Reagent: Protein
Instrument: Clinitek 500

Proposed Device	300	0	0	0	1	168
	100	0	0	3	104	0
	30	0	0	139	5	0
	Trace	0	177	4	0	0
	Neg	903	10	0	0	0
	Protein	Neg	Trace	30	100	300
		Predicate Device				

Reagent: Protein
Instrument: Visual

Proposed Device	≥ 2000	0	0	0	0	0	125
	300	0	0	0	1	49	0
	100	0	0	0	105	0	0
	30	0	0	141	0	0	0
	Trace	0	178	0	0	0	0
	Neg	915	0	0	0	0	0
	Protein	Neg	Trace	30	100	300	≥ 2000
		Predicate Device					

For ketones, the company determined:

Reagent: Ketones
Instrument: Clinitek 50

Proposed Device	**Large**	0	0	0	2	176
	Mod	0	0	2	117	1
	Small	0	3	114	2	0
	Trace	0	190	2	0	0
	Neg	898	7	0	0	0
	Ketones	**Neg**	**Trace**	**Small**	**Mod**	**Large**
		Predicate Device				

Reagent: Ketones
Instrument: Clinitek 100

Proposed Device	**Large**	0	0	0	0	175
	Mod	0	0	4	108	2
	Small	0	2	135	4	0
	Trace	1	173	2	0	0
	Neg	904	4	00	0	0
	Ketones	**Neg**	**Trace**	**Small**	**Mod**	**Large**
		Predicate Device				

Reagent: Ketones
Instrument: Clinitek 200

Proposed Device	**Large**	0	0	0	1	172
	Mod	0	0	2	108	4
	Small	0	2	134	4	0
	Trace	0	174	3	0	0
	Neg	903	7	0	0	0
	Ketones	**Neg**	**Trace**	**Small**	**Mod**	**Large**
		Predicate Device				

Reagent: Ketones
Instrument: Clinitek 500

Proposed Device	Large	0	0	0	3	170
	Mod	0	0	1	118	3
	Small	0	6	119	2	0
	Trace	0	182	2	0	0
	Neg	902	6	0	0	0
	Ketones	Neg	Trace	Small	Mod	Large
		Predicate Device				

Reagent: Ketones
Instrument: Visual

Proposed Device	Large	0	0	0	2	172
	Mod	0	0	1	117	2
	Small	0	3	126	3	0
	Trace	0	182	5	0	0
	Neg	896	5	0	0	0
	Ketones	Neg	Trace	Small	Mod	Large
		Predicate Device				

For urobilinogen, the company determined:

Reagent: Urobilinogen
Instrument: Clinitek 50

Proposed Device	8	0	0	0	1	151
	4	0	0	11	117	0
	2	0	5	143	2	0
	1	1	188	3	0	0
	0.2	889	3	0	0	0
	Urobilinogen	0.2	1	2	4	8
		Predicate Device				

Reagent: Urobilinogen
Instrument: Clinitek 100

Proposed Device	**8**	0	0	0	4	138
	4	0	0	0	116	8
	2	0	3	154	3	0
	1	1	183	3	0	0
	0.2	891	10	0	0	0
	Urobilinogen	**0.2**	**1**	**2**	**4**	**8**
		Predicate Device				

Reagent: Urobilinogen
Instrument: Clinitek 200

Proposed Device	**8**	0	0	0	5	150
	4	0	0	2	113	2
	2	0	5	146	0	0
	1	0	196	0	0	0
	0.2	885	10	0	0	0
	Urobilinogen	**0.2**	**1**	**2**	**4**	**8**
		Predicate Device				

Reagent: Urobilinogen
Instrument: Clinitek 500

Proposed Device	**8**	0	0	0	4	151
	4	0	0	0	115	0
	2	0	3	147	1	0
	1	1	190	2	0	0
	0.2	888	12	0	0	0
	Urobilinogen	**0.2**	**1**	**2**	**4**	**8**
		Predicate Device				

Reagent: Urobilinogen
Instrument: Visual

Proposed Device	**8**	0	0	0	3	154
	4	0	0	4	110	2
	2	0	4	150	3	0
	1	0	189	3	0	0
	0.2	884	8	0	0	0
	Urobilinogen	**0.2**	**1**	**2**	**4**	**8**
		Predicate Device				

For bilirubin, the company determined:

Reagent: Bilirubin
Instrument: Clinitek 50

Proposed Device	**Lg**	0	0	9	119
	Med	0	12	102	10
	Sm	5	360	14	0
	Neg	883	0	0	0
	Bilirubin	**Neg**	**Sm**	**Med**	**Lg**
		Predicate Device			

Reagent: Bilirubin
Instrument: Clinitek 100

Proposed Device	**Lg**	0	0	4	116
	Med	0	2	120	16
	Sm	4	361	12	0
	Neg	873	6	0	0
	Bilirubin	**Neg**	**Sm**	**Med**	**Lg**
		Predicate Device			

Reagent: Bilirubin
Instrument: Clinitek 200

Proposed Device	**Lg**	0	0	3	122
	Med	0	5	112	12
	Sm	0	371	4	0
	Neg	882	3	0	0
	Bilirubin	**Neg**	**Sm**	**Med**	**Lg**
		Predicate Device			

Reagent: Bilirubin
Instrument: Clinitek 500

Proposed Device	**Lg**	0	0	2	120
	Med	0	0	122	3
	Sm	0	383	3	0
	Neg	871	10	0	0
	Bilirubin	**Neg**	**Sm**	**Med**	**Lg**
		Predicate Device			

Reagent: Bilirubin
Instrument: Visual

Proposed Device	**Lg**	0	0	4	125
	Med	0	0	121	13
	Sm	4	357	7	0
	Neg	875	8	0	0
	Bilirubin	**Neg**	**Sm**	**Med**	**Lg**
		Predicate Device			

For pH, the company determined:

Reagent: pH
Instrument: Clinitek 50

Proposed Device	**8.5**	0	0	0	0	0	2	14	128
	8.0	0	0	0	0	2	7	177	20
	7.5	0	0	0	0	18	163	6	0
	7.0	0	0	2	16	154	27	0	0
	6.5	0	0	12	185	6	0	0	0
	6.0	5	7	183	4	0	0	0	0
	5.5	12	160	7	1	0	0	0	0
	5.0	191	5	0	0	0	0	0	0
	pH	**5.0**	**5.5**	**6.0**	**6.5**	**7.0**	**7.5**	**8.0**	**8.5**
		Predicate Device							

Reagent: pH
Instrument: Clinitek 100

Proposed Device	**8.5**	0	0	0	0	0	0	18	143
	8.0	0	0	0	0	0	12	170	3
	7.5	0	0	0	4	23	157	16	0
	7.0	0	0	0	4	163	4	0	0
	6.5	0	5	13	192	17	13	0	0
	6.0	0	5	181	6	0	0	0	0
	5.5	11	152	7	8	0	0	0	0
	5.0	177	10	0	0	0	0	0	0
	pH	**5.0**	**5.5**	**6.0**	**6.5**	**7.0**	**7.5**	**8.0**	**8.5**
		Predicate Device							

Reagent: pH
Instrument: Clinitek 200

Proposed Device	8.5	0	0	0	0	0	0	8	143
	8.0	0	0	0	0	0	9	162	12
	7.5	0	0	0	0	2	176	2	0
	7.0	0	0	0	19	175	11	0	0
	6.5	0	0	3	194	3	0	0	0
	6.0	0	5	172	13	0	0	0	0
	5.5	5	178	14	2	0	0	0	0
	5.0	201	5	0	0	0	0	0	0
	pH	5.0	5.5	6.0	6.5	7.0	7.5	8.0	8.5
		Predicate Device							

Reagent: pH
Instrument: Clinitek 500

Proposed Device	8.5	0	0	0	0	0	0	5	180
	8.0	0	0	0	0	0	8	168	7
	7.5	0	0	0	0	2	177	5	0
	7.0	0	0	3	16	182	7	2	0
	6.5	0	0	9	179	5	0	0	0
	6.0	0	7	185	4	0	0	0	0
	5.5	5	164	6	0	0	0	0	0
	5.0	182	6	0	0	0	0	0	0
	pH	5.0	5.5	6.0	6.5	7.0	7.5	8.0	8.5
		Predicate Device							

Reagent: pH
Instrument: Visual

Proposed Device	8.5	0	0	0	0	0	0	23	237
	8.0	0	0	0	0	0	4	136	14
	7.5	0	0	0	1	13	150	2	4
	7.0	0	0	0	9	149	19	0	0
	6.5	0	1	3	167	21	2	0	0
	6.0	2	7	161	18	1	0	0	0
	5.5	4	163	13	0	0	0	0	0
	5.0	185	5	0	0	0	0	0	0
	pH	5.0	5.5	6.0	6.5	7.0	7.5	8.0	8.5
		Predicate Device							

For specific gravity, the company determined:

Reagent: SG
Instrument: Clinitek 50

Proposed Device	**1.030**	0	0	0	0	0	6	178
	1.025	0	0	0	0	0	224	14
	1.020	0	0	0	0	213	2	0
	1.015	0	0	3	269	1	0	0
	1.010	0	3	288	2	0	0	0
	1.005	0	284	2	0	0	0	0
	1.000	25	0	0	0	0	0	0
	Specific Gravity	**1.000**	**1.005**	**1.010**	**1.015**	**1.020**	**1.025**	**1.030**
		Predicate Device						

Reagent: SG
Instrument: Clinitek 100

Proposed Device	**1.030**	0	0	0	0	0	1	99
	1.025	0	0	0	0	12	191	2
	1.020	0	0	0	6	182	5	0
	1.015	0	0	3	270	0	0	0
	1.010	0	3	378	4	0	0	0
	1.005	0	326	7	0	0	0	0
	1.000	25	0	0	0	0	0	0
	Specific Gravity	**1.000**	**1.005**	**1.010**	**1.015**	**1.020**	**1.025**	**1.030**
		Predicate Device						

Reagent: SG
Instrument: Clinitek 200

Proposed Device	1.030	0	0	0	0	0	1	99
	1.025	0	0	0	0	7	190	2
	1.020	0	0	0	5	182	0	0
	1.015	0	0	14	270	1	0	0
	1.010	0	28	375	2	0	0	0
	1.005	0	310	3	0	0	0	0
	1.000	25	0	0	0	0	0	0
	Specific Gravity	1.000	1.005	1.010	1.015	1.020	1.025	1.030
		Predicate Device						

Reagent: SG
Instrument: Clinitek 500

Proposed Device	1.030	0	0	0	0	0	0	98
	1.025	0	0	0	0	17	194	0
	1.020	0	0	0	22	158	7	0
	1.015	0	0	21	238	3	0	0
	1.010	0	29	385	1	0	0	0
	1.005	0	307	9	0	0	0	0
	1.000	25	0	0	0	0	0	0
	Specific Gravity	1.000	1.005	1.010	1.015	1.020	1.025	1.030
		Predicate Device						

Reagent: SG
Instrument: Visual

Proposed Device	1.030	0	0	0	0	0	30	191
	1.025	0	0	0	0	9	194	0
	1.020	0	0	0	15	211	0	0
	1.015	0	0	1	270	6	0	0
	1.010	0	2	235	2	0	0	0
	1.005	0	315	8	0	0	0	0
	1.000	25	0	0	0	0	0	0
	Specific Gravity	1.000	1.005	1.010	1.015	1.020	1.025	1.030
		Predicate Device						

A summary of the company's findings:

Analyte	Test Method	Total	Agreement (%)
Glucose	Clinitek 50	1514	98.2
	Clinitek 100	1514	97.9
	Clinitek 200	1514	97.4
	Clinitek 500	1514	98.2
	Visual	1514	96.9

Analyte	Test Method	Total	Agreement (%)
Blood	Clinitek 50	1514	96.2
	Clinitek 100	1514	97.2
	Clinitek 200	1514	97.3
	Clinitek 500	1514	97
	Visual	1514	96.3
Leukocytes	Clinitek 50	1514	98.7
	Clinitek 100	1514	98.6
	Clinitek 200	1514	99.3
	Clinitek 500	1514	97.9
	Visual	1514	98.6
Nitrite	Clinitek 50	1514	99.7
	Clinitek 100	1514	98.2
	Clinitek 200	1514	99.6
	Clinitek 500	1514	99.7
	Visual	1514	98.2
Protein	Clinitek 50	1514	98.4
	Clinitek 100	1514	98.2
	Clinitek 200	1514	98.2
	Clinitek 500	1514	98.5
	Visual	1514	99.9
Ketones	Clinitek 50	1514	98.7
	Clinitek 100	1514	98.7
	Clinitek 200	1514	98.4
	Clinitek 500	1514	98.5
	Visual	1514	98.6
Urobilinogen	Clinitek 50	1514	98.2
	Clinitek 100	1514	97.9
	Clinitek 200	1514	98.4
	Clinitek 500	1514	98.5
	Visual	1514	98.2
Bilirubin	Clinitek 50	1514	96.7
	Clinitek 100	1514	97.1
	Clinitek 200	1514	98.2
	Clinitek 500	1514	98.8
	Visual	1514	97.6
pH	Clinitek 50	1514	88.6
	Clinitek 100	1514	88.2
	Clinitek 200	1514	92.5
	Clinitek 500	1514	93.6
	Visual	1514	89
Specific Gravity	Clinitek 50	1514	97.8
	Clinitek 100	1514	97.2
	Clinitek 200	1514	95.9
	Clinitek 500	1514	92.8
	Visual	1514	95.2

The data supplied by the company substantiates their claim for equivalence.

b. Matrix comparison:

Not applicable in this submission.

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 company indicated the following references ranges for the analytes detected with this device*:

Urobilinogen: 0 -1.0 mg/dL
Bilirubin: Negative on this device.
Ketone: Negative on this device.
Blood: Negative to "Trace"
Protein: Negative on this device.
Nitrite: Negative on this device.
Leukocytes: Negative on this device.
Glucose: Negative on this device.
Specific Gravity: 1.003-1.035.
pH: 4.6 to 8.0

*"European Urinalysis Guidelines", The Scandinavian Journal of Clinical & Laboratory Investigation, Scand J. Clin. Lab. Invest. Vol. 60-Supplement 231.2000.

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.