

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

A. 510(k) Number:

k082811

B. Purpose for Submission:

New device

C. Measurand:

Urine pH, blood, glucose, protein, ketone, urobilinogen, bilirubin, specific gravity, nitrite, ascorbic acid and leukocytes

D. Type of Test:

Qualitative and semi-quantitative

E. Applicant:

Urit Medical Electronic Co., Ltd.

F. Proprietary and Established Names:

Uritest 10G Urine Reagent Strips, Uritest 11G Urine Reagent Strips, Uritest 50 Urine Analyzer, Uritest -500B Urine Analyzer

G. Regulatory Information:

Classification Name	Product Code	Device Class	Regulation Number
Occult blood test	JIO	II	21 CFR §864.6550
Urinary glucose (non-quantitative) test system	JIL	II	21 CFR §862.1340
Urinary urobilinogen (non-quantitative) test system	CDM	I	21 CFR §862.1785
Urinary bilirubin and its conjugates (non-quantitative) test system	JJB	I	21 CFR §862.1115
Ketones (non-quantitative) test system	JIN	I	21 CFR §862.1435

Urinary protein or albumin (non-quantitative) test system	JIR	I	21 CFR §862.1645
Nitrite (non-quantitative) test system	JMT	I	21 CFR §862.1510
Leukocyte peroxidase test	LJX	I	21 CFR §864.7675
Urinary pH (non-quantitative) test system	CEN	I	21 CFR §862.1550
Ascorbic acid test system	JMA	I	21 CFR §862.1095
Specific Gravity	KSL	I	21 CFR §864.9320
Automated Urinalysis System	KQO	I	21 CFR §862.2900

4. Panel:

(75) Clinical Chemistry, (81) Hematology

H. Intended Use:

1. Intended use(s):

See indications for use below.

2. Indication(s) for use:

The Uritest-50 and Uritest-500B urine analyzers are semi-automated, bench top instruments which are intended for prescription, in vitro diagnostic use only. The instruments perform semi-quantitative detection of the following analytes in urine: leukocytes, ketone, nitrite, urobilinogen, bilirubin, protein, glucose, specific gravity, blood, pH and ascorbic acid. Test results may provide information regarding the status of carbohydrate metabolism, kidney and liver function, acid-base balance and bacteriuria. The instruments use the accompanying check strip for daily calibration.

Uritest 10G urine reagent strips provide semi-quantitative tests for leukocytes, ketone, nitrite, urobilinogen, bilirubin, protein, glucose, specific gravity, blood and pH in urine. The Uritest 10G urine reagent strips are for use with the Uritest-50 urine analyzer and are for prescription, in vitro diagnostic use only. Test results may provide information regarding the status of carbohydrate metabolism, kidney and liver function, acid-base balance and bacteriuria.

Uritest 11G urine reagent strips provide semi-quantitative tests for leukocytes, ketone, nitrite, urobilinogen, bilirubin, protein, glucose, specific gravity, blood, pH and ascorbic acid in urine. The Uritest 11G urine reagent strips are for use with Uritest-500B urine analyzer and are for prescription, in vitro diagnostic use only. Test results may provide information regarding the status of carbohydrate metabolism, kidney and liver function, acid-base balance and bacteriuria.

3. Special conditions for use statement(s):

Prescription use only

The test strips are not to be used for visual reading.

4. Special instrument requirements:

Uritest 50 and Uritest 500B urine analyzers

I. Device Description:

The Uritest-50 and Uritest-500B Urine Chemistry Analyzers are reflectance spectrophotometers that measure the reflectance from a Uritest 10G or Uritest 11G urine reagent strip for urinalysis. Both devices can display and print urinalysis results and can be connected to a laboratory computer for data management. Both analyzers are capable of reading the ascorbic acid pad on the Uritest 11G strip.

Uritest 10G strips and the Uritest 11G are dry chemistry reagent strips for use in urine. Both strips measure urine glucose, pH, urobilinogen, bilirubin, protein, specific gravity, ketone, blood, leukocyte esterase and nitrite. The Uritest 11G can also measure ascorbic acid.

J. Substantial Equivalence Information:

Device Name	Predicate Device Name	Predicate 510(k) number
Uritest 50	Bayer Clinitek 500	k926359
Uritest 500B	Bayer Clinitek 500	k926359
Uritest 10 G	Bayer Multistix 10 SG	k052719
Uritest 11G	Bayer Multistix 10 SG	k052719
Uritest 11G (ascorbic acid)	Diuri Uristik H-11	k040703
Uritest 50 (ascorbic acid)	Diuri H-500	k040703
Uritest 500B (ascorbic acid)	Diuri H-500	k040703

3. Comparison with predicate:

Item	Device	Predicate k926359	Predicate k040703 (ascorbic acid only)
	Uritest-50	Bayer Clinitek 500	Dirui H-500
Intended use	For use with Uritest 10G and 11G urine reagent strips for the semi-quantitative determination of Leukocytes, Ketones, Nitrite,	For use with Bayer Multistix 10 SG reagent strips for the semi-quantitative determination of	For use with URISTK H-11 reagent strips for the qualitative or semi-quantitative determination of

	Urobilinogen, Bilirubin, Protein, Glucose, Specific Gravity, Blood, pH and Ascorbic Acid.	Leukocytes, Ketones, Nitrite, Urobilinogen, Bilirubin, Protein, Glucose, Specific Gravity, Blood and pH.	Urobilinogen, Bilirubin, Ketone (acetoacetic acid), Blood, Protein, Nitrite, Leukocytes, Glucose, Specific Gravity, pH, and Ascorbic Acid.
General design	Bench-top instrument	Same	Same
Operating principle	Reflectance photometer	Same	Same
Calibration	Self-calibration---white calibration bar	Same	Same
Specimen ID enter	Manually enter or by bar code reader	Same	Same
Printer	Internal or external	Same	Same
Throughput	Single test mode: 60 tests/hour Continuous test mode: 120 tests/hour	500 tests/hour	514 strips/hour
Result report	Semi-quantitative symbol, SI or Conventional unit and plus system	Same	Same
Memory	1,000 results	500 patient results 200 control results	2000 patient results
Environment requirement	15°C-30°C, RH ≤ 80%	18°C -30°C, RH: 20% - 80%	18°C -30°C, RH ≤ 80%
Weight	2 Kg	7.4 Kg	6.8 Kg
Dimension	290 mm X 200 mm X 100 mm	324 mm X 377 mm X 282 mm	380 mm X 378 mm X 275 mm
Power source	DC 12V (Adapter), AC100-240V, 50/60Hz Power dissipation: 30VA	100-240VAC ±10%, 50-60Hz. Input: 72VA	100~240VAC, 50Hz/60Hz Power: 40VA

Item	Device	Predicate k926359	Predicate k040703 (ascorbic acid only)
	Uritest-500B	Bayer Clinitek 500	Dirui H-500
Intended use	For use with Uritest 10G and 11G urine reagent strips for the semi-quantitative determination of Leukocytes, Ketones, Nitrite, Urobilinogen, Bilirubin, Protein, Glucose, Specific Gravity, Blood, pH and	For use with Bayer Multistix 10 SG reagent strips for the semi-quantitative determination of Leukocytes, Ketones, Nitrite, Urobilinogen, Bilirubin, Protein,	For use with URISTK H-11 reagent strips for the qualitative or semi-quantitative determination of Urobilinogen, Bilirubin, Ketone (acetoacetic acid), Blood, Protein, Nitrite,

	Ascorbic Acid.	Glucose, Specific Gravity, Blood and pH.	Leukocytes, Glucose, Specific Gravity, pH, and Ascorbic Acid.
Design	Bench-top instrument	Same	Same
Operating principle	Reflectance photometer	Same	Same
Calibration	Self-calibration---white calibration bar	Same	Same
Specimen ID enter	Manually enter or by bar code reader	Same	Same
Printer	Internal or external	Same	Same
Throughput	500 tests/hour	500 tests/hour	514 strips/hour
Result report	Semi-quantitative symbol, SI or Conventional unit	Same	Same
Memory	1,000 results	500 patient results 200 control results	2000 patient results
Environment requirement	15°C-30°C, RH ≤ 80%	18°C -30°C, RH: 20% - 80%	18°C -30°C, RH ≤ 80%
Weight	6.5 Kg	7.4 Kg	6.8 Kg
Dimension	390 mm X 340 mm X 290 mm	324 mm X 377 mm X 282 mm	380 mm X 378 mm X 275 mm
Power source	AC100-240V, 50/60Hz Input: 61VA	100-240VAC ±10%, 50- 60Hz. Input: 72VA	100~240VAC, 50Hz/60Hz Power: 40VA

Reagent Strips

Item		Predicate k052719	Predicate k040703 (ascorbic acid only)
	Uritest 11G	Bayer Multistix 10SG	Dirui URISTIK H-11
Intended use	For semi-quantitative determination of certain constituents in urine by reflectance photometry with Uritest-50 or Uritest-500B Urine Analyzer. These measurements are useful in the evaluation of renal, urinary and metabolic disorders.	For semi-qualitative determination of certain constituents in urine either visually or by reflectance photometry with the Clinitek family Urine Analyzer. These measurements are useful in the evaluation of renal, urinary and metabolic disorders.	For qualitative and semi-qualitative determination of certain constituents in urine either visually or by reflectance photometry with the Dirui H-100 and H-500 Urine Analyzers. These measurements are useful in the evaluation of renal, urinary and metabolic disorders.
Analytes	Leukocytes, Ketones, Nitrite, Urobilinogen,	Leukocytes, Ketones, Nitrite, Urobilinogen,	Leukocytes, Ketones, Nitrite, Urobilinogen,

	Bilirubin, Protein, Glucose, Specific Gravity, Blood, pH and Ascorbic acid	Bilirubin, Protein, Glucose, Specific Gravity, Blood and pH	Bilirubin, Protein, Glucose, Specific Gravity, Blood, pH and Ascorbic acid
Specimen	Urine	Same	Same
Architecture	Firm plastic, dry reagent strips	Same	Same
Test principle	Ingredients that change color in reaction with analytes	Same	Same
Storage	Store at 2°C-30°C	At temperatures below 30°C do not freeze.	At temperatures below 30°C do not freeze.

-Item	Predicate k052719	
	Uritest 10G	Bayer Multistix 10 SG
Intended use	For semi-quantitative determination of certain constituents in urine by reflectance photometry with Uritest-50 or Uritest-500B Urine Analyzer. These measurements are useful in the evaluation of renal, urinary and metabolic disorders.	For semi-qualitative determination of certain constituents in urine either visually or by reflectance photometry with the Clinitek family Urine Analyzer. These measurements are useful in the evaluation of renal, urinary and metabolic disorders.
Analytes	Leukocytes, Ketones, Nitrite, Urobilinogen, Bilirubin, Protein, Glucose, Specific Gravity, Blood, and pH	Leukocytes, Ketones, Nitrite, Urobilinogen, Bilirubin, Protein, Glucose, Specific Gravity, Blood and pH
Specimen	Urine	Same
Architecture	Firm plastic, dry reagent strips	Same
Test principle	Ingredients that change color in reaction with analytes	Same
Storage	Store at 2°C-30°C	At temperatures below 30°C do not freeze.

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

EN 61000-3-2:2000+A2:A2005 Harmonic Current Test

EN 61000-3-3:1995+A1:2001, Voltage Fluctuations and Flicker Test

EN 61010-1:2001, Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use Part 1: General Requirements

L. Test Principle:

Uritest 50 and Uritest 500B

The Uritest 50 and Uritest 500B utilize reflectance photometry to measure the concentration of various urine chemical compounds and constituents. A urine wetted reagent strip is placed into the instrument(s) causing a color change in the test pads. The degree of color development on the pads is proportional to the concentration of the urine analyte. The strip passes under a LED light source. As the pad darkens in color, more light is absorbed and less is reflected. The reflected light is filtered at specific wavelengths corresponding to the reflected colors on the test pads. It is converted by the optical-electronic sensor system into electrical signals which are then converted into concentration units and printed.

Uritest 10G and Uritest 11G Test Strips

Leukocytes: The test reveals the presence of granulocyte esterases. These esterases cleave an indoxyl ester, and the indoxyl so liberated reacts with a diazonium salt to produce a violet dye. Leukocyte esterase results may be positive in the absence of observable cells if the leukocytes have lysed. Positive results may occasionally be found with random specimens from females due to contamination of the specimen by vaginal discharge. Elevated glucose concentrations (1000-2000mg/dL) or high specific gravity may cause decreased test results. The presence of cephalixin, cephalothin, tetracycline may cause decreased reactivity, and high levels of the drug may cause a false negative reaction. Reactivity may also vary with temperature. The test area does not react with lymphocyte.

Ketone: This test is based on the principle of Legal's test and is more sensitive to acetoacetic acid than to acetone. The reagent area does not react with β -hydroxybutyric acid. Some high specific gravity/low pH urines may give reactions up to and including Trace. Normal urine specimens usually yield negative results with this reagent. False positive results (Trace) may occur with highly pigmented urine specimens or those containing large amounts or levodopa metabolites.

Nitrite: The test is based on the principle of Griess's test and is specific to nitrite. Any degree of uniform pink colour development should be interpreted as a positive. Nitrite test area reacts singularly to the nitrite. Reacting color density does not correlate to number of existing bacteria. A negative result does not in itself prove that there is no significant bacteria. Negative results may occur when urinary tract infections are caused by organisms which do not contain reductase to convert nitrate to nitrite; when urine has not been retained in the bladder long enough (4-8hrs) for reduction of nitrate to occur; or when dietary nitrate is absent, even if organisms containing reductase are present and bladder incubation is ample. Ascorbic acid concentrations of 25mg/dL or greater may cause false negative results with specimens containing nitrite ion concentrations of 0.4mg/dL or less.

Urobilinogen: This test is based on the Ehrlich reaction.

The reagent area may react with interfering substances known to react with Ehrlich's reagent. Excreted pigments and medicaments that have a red intrinsic coloration in acidic medium may produce false positive results. This test is inhibited by elevated concentrations of formaldehyde. Strip reactivity increases with temperature increasing; the optimum temperature is 22°C to 26°C. The absence of urobilinogen cannot be determined with this

test.

Bilirubin: This test is based on the coupling of bilirubin with diazonium salt in an acid medium. Normally no bilirubin is detectable in urine by even the most sensitive methods. Even trace amounts of bilirubin are sufficiently abnormal to require further investigation. Some urine constituents (medicines, urinary indicants) may produce a yellowish or reddish discoloration of the test paper that may interfere with interpreting the result. Ascorbic acid concentrations of 100mg/dL or greater may cause false negatives.

Protein: The test is based on the principle of the protein error of a pH indicator. The reagent area is more sensitive to albumin. An elevated pH (up to 9) may affect the test. The residues of disinfectants containing quaternary ammonium groups or chlorohexidine are present in the urine vessel maybe lead to a false positive result.

Glucose: The test is based on the specific glucose oxidase/peroxidase reaction. The test is specific for glucose, no substance excreted in urine other than glucose is known to give a positive result. Ascorbic acid of more than 45mg/dL and/or high Ketone concentrations (80mg/dL) may cause false negatives for specimens containing small amounts of glucose (100mg/dL). The reactivity of the glucose test decreases as the SG of the urine increases. False positive reactions may be caused by hypochlorite or peroxide (cleaning agents). Reactivity may also vary with temperature.

Specific Gravity: This test contains a detergent and Bromthymol blue that indicates the presence of ionic constituents in the urine by changing color from green to yellow. The specific gravity test permits determination of urine specific gravity between 1.005 and 1.030. In general, it correlates within 0.005 with values obtained with the refractive index method. Strips are automatically adjusted for pH by the instrument when $\text{pH} \geq 7.0$ or $\text{pH} \leq 5.0$. Highly buffered alkaline urine may cause low readings relative to other methods. Elevated specific gravity readings may be obtained in the presence of moderate quantities (500mg/dL) of protein.

Blood: Hemoglobin and myoglobin catalyze the oxidation of the indicator by means of organic hydroperoxide contained in the test paper. This test is highly sensitive to hemoglobin and thus complements microscopic examination. The sensitivity of this test may be reduced in urine with high specific gravity. The test is equally sensitive to myoglobin as to hemoglobin. Captopril and Lodine may also cause decreased reactivity. Blood is often found in the urine of menstruating females. Certain oxidizing contaminants, such as hypochlorite, may produce false positive results. Microbial peroxidase associated with urinary tract infection may cause a false positive reaction. Ascorbic acid concentrations greater than 25mg/dL may cause false negatives at the trace levels.

pH : This test contains a mixed indicator which assures a marked change in colour between pH4.5 and pH9.

Ascorbic Acid (Uritest 11G only): The test involves the decolorization of Tillman's reagent. False positive results may occur.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Repeatability (within run) precision of both analyzers was evaluated by using negative urines and spiked urines of known concentrations for each analyte. Each sample was tested 20 times across 3 instruments with the Uritest 10G or Uritest 11G strips for a total of 60 measurements at each concentration. All concentrations for all tests had 60 of 60 (100%) match at \pm one color block.

Uritest 50

Test	Expected Value					
	- (0)	\pm (15)	+1 (70)	+2 (125)	+3 (500)	
Leukocyte (leu/mcL)						
Exact agreement	60/60	60/60	54/60	60/60	60/60	
\pm 1 color block	60/60	60/60	60/60	60/60	60/60	
Nitrite	Negative	Positive				
Exact agreement	60/60	60/60				
\pm 1 color block	60/60	60/60				
Ketone (mg/dL)	- (0)	\pm (5)	+1 (15)	+2 (40)	+3 (\geq 80)	
Exact agreement	60/60	52/60	60/60	50/60	52/60	
\pm 1 color block	60/60	60/60	60/60	60/60	60/60	
Blood (ery/mcL)	- (0)	\pm (10)	+1 (25)	+2 (80)	+3 (200)	
Exact agreement	60/60	60/60	60/60	60/60	52/60	
\pm 1 color block	60/60	60/60	60/60	60/60	60/60	
Bilirubin (mg/dL)	- (0)	+1 (0.5)	+2 (2)	+3 (6)		
Exact agreement	60/60	56/60	60/60	54/60		
\pm 1 color block	60/60	60/60	60/60	60/60		
Urobilinogen (EU/dL)	Normal	+1 (2.0)	+2 (4.0)	+3(\geq 8.0)		
Exact agreement	60/60	60/60	54/60	60/60		
\pm 1 color block	60/60	60/60	60/60	60/60		
Protein (mg/dL)	- (0)	\pm (15)	+1 (30)	+2 (100)	+3 (300)	
Exact agreement	60/60	58/60	60/60	60/60	39/60	
\pm 1 color block	60/60	60/60	60/60	60/60	60/60	
Glucose (mg/dL)	- (0)	\pm (50)	+1 (100)	+2(250)	+3(500)	+4(\geq 1000)
Exact agreement	60/60	52/60	60/60	48/60	60/60	60/60
\pm 1 color block	60/60	60/60	60/60	60/60	60/60	60/60
Specific Gravity	1.005	1.010	1.015	1.020	1.025	1.030
% Exact agreement	60/60	53/60	60/60	52/60	40/60	60/60
% \pm 1 color block	60/60	60/60	60/60	60/60	60/60	60/60
pH	5.0	6.0	7.0	8.0	8.5	9.0
Exact agreement	48/60	34/60	24/60	60/60	42/60	100
\pm 1 color block	60/60	60/60	60/60	60/60	60/60	60/60
Ascorbic Acid (mg/dL)	- (0)	\pm (10)	+1 (25)	+2 (50)	+3 (100)	
Exact agreement	60/60	58/60	60/60	60/60	52/60	
\pm 1 color block	60/60	60/60	60/60	60/60	60/60	

Uritest—500B

Test	Expected Value					
Leukocyte (leu/mcL)	- (0)	± (15)	+1 (70)	+2 (125)	+3 (500)	
Exact agreement	60/60	60/60	54/60	56/60	60/60	
± 1 color block	60/60	60/60	60/60	60/60	60/60	
Nitrite	Negative	Positive				
Exact agreement	60/60	60/60				
± 1 color block	60/60	60/60				
Ketone (mg/dL)	- (0)	± (5)	+1 (15)	+2 (40)	+3 (≥ 80)	
Exact agreement	60/60	50/60	60/60	48/60	58/60	
± 1 color block	60/60	60/60	60/60	60/60	60/60	
Blood (ery/mcL)	- (0)	± (10)	+1 (25)	+2 (80)	+3 (200)	
Exact agreement	60/60	57/60	60/60	60/60	59/60	
± 1 color block	60/60	60/60	60/60	60/60	60/60	
Bilirubin (mg/dL)	- (0)	+1 (0.5)	+2 (2)	+3 (6)		
Exact agreement	60/60	60/60	60/60	54/60		
± 1 color block	60/60	60/60	60/60	60/60		
Urobilinogen (EU/dL)	Normal	+1 (2.0)	+2 (4.0)	+3(≥ 8.0)		
Exact agreement	60/60	58/60	60/60	60/60		
± 1 color block	60/60	60/60	60/60	60/60		
Protein (mg/dL)	- (0)	± (15)	+1 (30)	+2 (100)	+3 (300)	
Exact agreement	60/60	60/60	60/60	60/60	45/60	
± 1 color block	60/60	60/60	60/60	60/60	60/60	
Glucose (mg/dL)	- (0)	± (50)	+1 (100)	+2(250)	+3(500)	+4(≥ 1000)
Exact agreement	60/60	60/60	60/60	44/60	60/60	60/60
± 1 color block	60/60	60/60	60/60	60/60	60/60	60/60
Specific Gravity	1.005	1.010	1.015	1.020	1.025	1.030
Exact agreement	60/60	48/60	60/60	58/60	45/60	60/60
± 1 color block	60/60	60/60	60/60	60/60	60/60	60/60
pH	5.0	6.0	7.0	8.0	8.5	9.0
Exact agreement	42/60	60/60	58/60	60/60	34/60	60/60
± 1 color block	60/60	60/60	60/60	60/60	60/60	60/60
Ascorbic Acid (mg/dL)	- (0)	± (10)	+1 (25)	+2 (50)	+3 (100)	
Exact agreement	60/60	60/60	60/60	60/60	56/60	
± 1 color block	60/60	60/60	60/60	60/60	60/60	

Precision was determined using two levels of commercially available control material. One lot each of Uritest 10G and Uritest 11G strips was used on one Uritest-50 and Uritest-500B. Tests were performed in replicates of 10 for 2 runs on each analyzer for 10 days.

Uritest-50 N=negative, P=positive

Analyte	Level 1				Level 2			
	Expected values	Test results	% Agreement	n	Expected values	Test results	% Agreement	N
Leukocytes	N	N	100	400	±-2+	±-1+	100	400
Ketone	N	N	100	400	±-2+	1+	100	400
Nitrite	N	N	100	400	P	P	100	400
Urobilinogen	N	N	100	400	2+-3+	2+-3+	100	400
Bilirubin	N	N	100	400	2+-3+	3+	100	400
Protein	N	N	100	400	2+-3+	3+	100	400
Glucose	N	N	100	400	2+-4+	3+-4+	100	400
Specific Gravity	1.010-1.020	1.010-1.015	100	400	1.015-1.025	1.015-1.025	100	400
Blood	N	N	100	400	2+-3+	3+	100	400
pH	5.0-6.0	5.5-6.0	100	400	6.5-7.5	6.5-7.0	100	400

Uritest-500B N=negative, P=positive

Analyte	Level 1				Level 2			
	Expected values	Test results	% Agreement	n	Expected values	Test results	% Agreement	N
Leukocytes	N	N	100	400	±-2+	±-1+	100	400
Ketone	N	N	100	400	±-2+	1+	100	400
Nitrite	N	N	100	400	P	P	100	400
Urobilinogen	N	N	100	400	2+-3+	2+-3+	100	400
Bilirubin	N	N	100	400	2+-3+	3+	100	400
Protein	N	N	100	400	2+-3+	3+	100	400
Glucose	N	N	100	400	2+-4+	3+-4+	100	400
Specific Gravity	1.010-1.020	1.010-1.015	100	400	1.015-1.025	1.015-1.025	100	400
Blood	N	N	100	400	2+-3+	3+	100	400
pH	5.0-6.0	5.5-6.0	100	400	6.5-7.5	6.5-7.0	100	400
Ascorbic Acid	N	N	100	400	N	N	100	400

b. Linearity/assay reportable range:

A study was performed to test the measuring range on the Uritest 50 analyzer and Uritest 500 analyzer using one lot of Uritest 10G and Uritest 11G strips in replicates of 10. Samples were created by spiking negative urine with known concentrations of each substance or by serial dilution of a high concentration with a negative urine. Specimens were adjusted the match the concentration for each particular color pad on

the strip. Negative samples were not tested. See section M.1.a. Repeatability studies for negative samples. Results are summarized below.

Uritest-50 with Uritest 10G

Test	Exact Match	%	± 1 Color Block	%
pH	37/50	74	50/50	100
Glucose	38/50	88	50/50	100
Specific Gravity	56/60	93	60/60	100
Nitrite	10/10	100	10/10	100
Blood	34/40	85	40/40	100
Protein	37/40	93	40/40	100
Bilirubin	28/30	93	30/30	100
Urobilinogen	26/30	87	30/30	100
Ketone	37/40	93	40/40	100
Leukocyte esterase	37/40	93	40/40	100
Ascorbic acid (11G)	35/40	88	40/40	100

Uritest-500B with Uritest 11G

Test	Exact Match	%	± 1 Color Block	%
pH	31/50	62	50/50	100
Glucose	38/50	88	50/50	100
Specific Gravity	54/60	88	60/60	100
Nitrite	10/10	100	10/10	100
Blood	34/40	85	40/40	100
Protein	39/40	98	40/40	100
Bilirubin	29/30	97	30/30	100
Urobilinogen	27/30	90	30/30	100
Ketone	40/40	100	40/40	100
Leukocyte esterase	33/40	83	40/40	100
Ascorbic acid	33/40	83	40/40	100

The reportable ranges for the Uritest -50 and Uritest-500B are:

Test	Reportable Range
pH	5.0-9.0
Glucose	Neg.-1000 mg/dL
Specific Gravity	1.005-1.030
Nitrite	Neg-Pos
Blood	Neg-200 ery/micL
Protein	Neg-300 mg/dL
Bilirubin	Neg-6 mg/dL
Urobilinogen	2-8 E.U/dL
Ketone	Neg-80 mg/dL
Leukocyte esterase	Neg-500 leu/micL
Ascorbic acid	Neg -100 mg/dL

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

The sponsor recommends using commercially available control materials for use on the Uritest 50 and Uritest-500B urine analyzers.

Calibration verification is performed using Check Strips which are included with the analyzers. These are white strips which check the remittance values for each test. Recommendations for calibration verification are included in the operator’s manual for each analyzer.

Real time stability studies were performed for the Uritest 10G and Uritest 11G test strips over a 21 month period. The test strips were stored at 2° C-8° C and 30° C. Strips were tested quarterly with negative and spiked positive urine samples on the Uritest 50 and Uritest 500 Urine Analyzers. Data demonstrated that the test strips met the sponsor’s claimed shelf-life of 18 months at 2°C-30°C and <= 80% Relative Humidity.

d. *Detection limit:*

Analytical sensitivities of the Uritest 10G and Uritest 11G strips on the Uritest 50 and Uritest-500B were evaluated by spiking urine with known concentrations of each analyte and then diluting these samples with a negative urine to establish the range where the strip went from negative readings to positive readings. Each concentration was tested 10 times on each analyzer using each strip type. The upper limit of sensitivity was defined as the cutoff at which 100% of the test results were trace or positive. The sensitivities for both analyzers and both strips were identical. pH and specific gravity do not have lower limits of sensitivity. See section M.1.b.

Analyte	10G		11G		Sensitivity range
	Lowest sensitivity	Highest sensitivity	Lowest sensitivity	Highest sensitivity	
Leukocytes	15 leu/mcL	40 leu/mcL	15 leu/mcL	40 leu/mcL	15-40 leu/mcL
Uritest 50 Negative	2	0	3	0	
Trace (15 cells/mcL)	8	10	7	10	
Uritest 500B Negative	3	0	3	0	
Trace (15 cells/mcL)	7	10	7	10	
Ketone	5 mg/dL	10 mg/dL	5 mg/dL	10 mg/dL	5.0-10.0 mg/dL
Uritest 50 Negative	2	0	2	0	
Trace (5 mg/dL)	8	10	8	10	
Uritest 500B Negative	1	0	1	0	
Trace (5 mg/dL)	9	10	9	10	

Nitrites	Lowest sensitivity 0.15 mg/dL	Highest sensitivity 0.2 mg/dL	Lowest sensitivity 0.15 mg/dL	Highest sensitivity 0.2 mg/dL	0.15-0.2 mg/dL (Neg/Pos)
Uritest 50 Negative	1	0	2	0	
Positive	9	10	8	10	
Uritest 500B Negative	2	0	2	0	
Positive	8	10	8	10	
Urobilinogen	Lowest sensitivity 1.0 EU/dL	Highest sensitivity 2.0 EU/dL	Lowest sensitivity 1.0 EU/dL	Highest sensitivity 2.0 EU/dL	1.5-2.0 EU/dL
Uritest 50 Negative	3	0	3	0	
1+ (2 EU/dL)	7	10	7	10	
Uritest 500B Negative	2	0	3	0	
1+ (2 EU/dL)	8	10	7	10	

Analyte	10G		11G		Sensitivity range
Bilirubin	Lowest sensitivity 0.5 mg/dL	Highest sensitivity 1.0 mg/dL	Lowest sensitivity 0.5 mg/dL	Highest sensitivity 1.0 mg/dL	0.5-1.0 mg/dL
Uritest 50 Negative	3	0	3	0	
1+ (0.5 mg/dL)	7	10	7	10	
Uritest 500B Negative	5	0	4	0	
1+ (0.5 mg/dL)	5	10	6	10	
Blood	Lowest sensitivity 5 Ery/mcL	Highest sensitivity 15 Ery/mcL	Lowest sensitivity 5 Ery/mcL	Highest sensitivity 15 Ery/mcL	5-15 Ery/mcL
Uritest 50 Negative	2	0	2	0	
Trace (10 ery/micL)	8	10	8	10	
Uritest 500B Negative	1	0	2	0	
Trace (10 ery/micL)	9	10	8	10	
Protein	Lowest sensitivity 10 mg/dL	Highest sensitivity 30 mg/dL	Lowest sensitivity 10 mg/dL	Highest sensitivity 30 mg/dL	10-30 mg/dL
Uritest 50 Negative	7	0	8	0	
Trace (15 mg/dL)	3	10	2	10	
Uritest 500B Negative	8	0	8	0	
Trace (15 mg/dL)	2	10	2	10	
Glucose	Lowest sensitivity 40 mg/dL	Highest sensitivity 50 mg/dL	Lowest sensitivity 40 mg/dL	Highest sensitivity 50 mg/dL	40-50 mg/dL
Uritest 50 Negative	2	0	2	0	
Trace (50 mg/dL)	8	10	8	10	
Uritest 500B Negative	1	0	2	0	
Trace (50 mg/dL)	9	10	8	10	

Ascorbic Acid		Lowest sensitivity 10 mg/dL	Highest sensitivity 14 mg/dL	10-14 mg/dL
Uritest 50 Negative		5	0	
Trace (10 mg/dL)		5	10	
Uritest 500B Negative		4	0	
Trace (10 mg/dL)		6	10	

e. Analytical specificity:

Fresh negative urine was spiked with possible interfering substances at various interferent concentrations and analyzed in replicates of 10 using the Uritest 10G and 11G strips on the Uritest 50 and Uritest 500B analyzers. The concentration where interference is observed and its effect on various tests is summarized below:

Test	Interfering substances	Impact on test
Leukocytes	Elevated glucose(1000-2000 mg/dL)	Lower reported leu/uL
	High specific gravity (>1.025)	Lower reported leu/uL
	Low temperature(<20°C)	Lower reported leu/uL
Ketone	Levodopa metabolites	False positive (Trace)
Nitrite	Ascorbic acid(>25mg/dL)	False negative
Urobilinogen	Excreted pigment	False positive
Bilirubin	Ascorbic acid(>100mg/dL)	False negative
Protein	Elevated pH (up to 9)	False positive
	Quaternary ammonium	False positive
Glucose	Ascorbic acid (>45mg/dL)	False negative
	High Ketone (80mg/dL)	False negative
	Peroxide	False positive
Specific gravity	Elevated protein (>500mg/dL)	High specific gravity
Blood	Ascorbic acid(>25mg/dL)	False negatives
	Microbial peroxidase	False positive
pH	Bacterial contamination/overgrowth may cause elevated pH	False increase
Ascorbic acid	Other reducing agents, specifically sodium thiosulfate, cysteine	False positive

Interfering substances and their effects on the various reagent strip analytes are presented in the labeling.

f. Assay cut-off:

Not applicable

2. Comparison studies:

a. *Method comparison with predicate device:*

The clinical study was performed at three different clinical sites over 10 days. Three intended users operated the devices at each site (n=9). 321 out-patients were enrolled in the study: 104 subjects at Site 1, 102 subjects at Site 2 and 115 subjects at Site 3. The users used the labeling to perform the testing.

The sponsor also used 19 spiked urine samples in the study (N=340). 5 spiked samples at the Site 1, 9 spiked samples at the Site 2 and 5 spiked samples at Site 3. Among these samples, about 25%~35% positive samples were covered for each analyte with majority of values at the cutoff. Both subject urine samples and spiked urine samples at each clinical site were tested both on Uritest 10G, Uritest 11G and Bayer Multistix 10SG using the respective urine analyzer for each system.

The comparisons were as follows with the following note below:
Glucose has different test pad concentrations between the candidate devices and the predicate devices. The differences are summarized below:

Glucose (mg/dL)		—	±	1+	2+	3+	4+
	Bayer	0	100	250	500	1000	----
	Uritest	0	50	100	250	500	1000

In addition, the sponsor performed ascorbic acid comparisons between the Uritest 50 and the Uritest 500B against the Dirui H-500 Urine Analyzer (k040703) on 216 samples at three sites using three intended users per site. The site combined results are below:

1) **Uritest-50 with Uritest 11G VS. Dirui H-500**

	Ascorbic Acid	Predicate device				
		—(0)	±(10)	1+(25)	2+(50)	3+(100)
Proposed device	3+(100)				1	12
	2+(50)		1	2	13	
	1+(25)		1	16	2	
	±(10)	1	20	1		
	—(0)	144	2			
Total		145	24	19	16	12
% Agreement (exact match)		99	83	84	81	100
% Agreement (± 1 color block)		100	96	100	100	100

2) **Uritest-500B with Uritest 11G VS. Dirui H-500**

	Ascorbic Acid	Predicate device				
		-(0)	±(10)	1+(25)	2+(50)	3+(100)
Proposed device	3+(100)			1	1	12
	2+(50)			1	13	
	1+(25)		2	16	2	
	±(10)	1	21	1		
	-(0)	144	1			
Total		145	24	19	16	12
% Agreement (exact match)		99	88	84	81	100
% Agreement (±1 color block)		100	100	95	100	100

3). **Uritest-50 with Uritest 10G VS. Clinitek 500 with Multistix 10SG**

	LEU	Predicate device				
		-	±	+1	+2	+3
Proposed device	+3				1	16
	+2			6	13	1
	+1		4	22	1	
	±	1	34	3		
	-	236	2			
Total		237	40	31	15	17
% Agreement (exact match)		99	85	71	87	94
% Agreement (±1 color block)		100	100	100	100	100

	NIT	Predicate device	
		-	+
Proposed device	+		91
	-	248	1
Total		248	92
% Agreement (exact match)		100	99
% Agreement (±1 color block)		100	100

	KET	Predicate device				
		—	±	+1	+2	+3
Proposed device	+3					11
	+2			1	9	
	+1			17	3	
	±		49	2		
	—	247	1			
Total		247	50	20	12	11
% Agreement (exact match)		100	98	85	75	100
% Agreement (±1 color block)		100	100	100	100	100

For occult blood, test results were:

	BLD	Predicate device				
		—	±	+1	+2	+3
Proposed device	+3					19
	+2				18	3
	+1			17	5	1
	±		39	5		
	—	220	12	1		
Total		220	51	23	23	23
% Agreement (exact match)		100	76	74	78	83
% Agreement (±1 color block)		100	100	96	100	96

	BIL	Predicate device			
		—	+1	+2	+3
Proposed device	+3				12
	+2			19	1
	+1		51	1	
	—	252	4		
Total		252	55	20	13
% Agreement (exact match)		100	93	95	92
% Agreement (±1 color block)		100	100	100	100

	URO	Predicate device			
		Normal (0.2/1.0)	+1 (2.0)	+2 (4.0)	+3 (≥8.0)
Proposed device	+3				11
	+2		1	24	
	+1		51		
	Normal	250	3		
Total		250	55	24	11
% Agreement (exact match)		100	93	100	100
% Agreement (±1 color block)		100	100	100	100

	PRO	Predicate device				
		—	±	+1	+2	+3
Proposed device	+3					15
	+2				15	
	+1			16	4	
	±		46	3	2	
	—	232	6	1		
Total		232	52	20	21	15
% Agreement (exact match)		100	88	80	71	100
% Agreement (±1 color block)		100	100	95	90	100

	GLU	Predicate device (mg/dl)				
		—	± (100)	+1 (250)	+2 (500)	+3 (1000)
Proposed device (mg/dl)	+4 (1000)					13
	+3 (500)				13	3
	+2 (250)		1	15	2	
	+1 (100)		31	1		
	± (50)		6			
	—	255				
Total		255	38	16	15	16
% Agreement (exact match)		100	82	94	87	81
% Agreement (±1 color block)		100	100	100	100	100

	SG	Predicate device					
		1.005	1.010	1.015	1.020	1.025	1.030
Proposed device	1.030					4	42
	1.025			1	1	58	6
	1.020			10	71	7	
	1.015		4	41	21		
	1.010	4	45	2	2		
	1.005	15	6				
Total		19	55	54	95	69	48
% Agreement (exact match)		79	82	76	75	84	88
% Agreement (± 1 color block)		100	100	98	98	100	100

	pH	Predicate device								
		5.0	5.5	6.0	6.5	7.0	7.5	8.0	8.5	9.0
Proposed device	9.0									4
	8.5								5	
	8.0						1	6		
	7.5					4	12			
	7.0				3	32	4			
	6.5			2	32	7				
	6.0			143	15	1				
	5.5	4	20	27						
	5.0	13	4	1						
Total		17	24	173	50	44	17	6	5	4
% Agreement (exact match)		76	83	83	64	73	71	100	100	100
% Agreement (± 1 color block)		100	100	99	100	99	100	100	100	100

4). Uritest-500B with Uritest 11G VS. Clinitek 500 with Multistix 10SG

	LEU	Predicate device				
		-	\pm	+1	+2	+3
Proposed device	+3					16
	+2			2	15	1
	+1		3	24		
	\pm	1	35	5		
	-	236	2			
Total		237	40	31	15	17
% Agreement (exact		99	88	77	100	94

match)					
% Agreement (± 1 color block)	100	100	100	100	100

	NIT	Predicate device	
		-	+
Proposed device	+		92
	-	248	
Total		248	92
% Agreement (exact match)		100	100
% Agreement (± 1 color block)		100	100

	KET	Predicate device				
		-	\pm	+1	+2	+3
Proposed device	+3					11
	+2			2	12	
	+1			16		
	\pm		49	2		
	-	247	1			
Total		247	50	20	12	11
% Agreement (exact match)		100	98	80	100	100
% Agreement (± 1 color block)		100	100	100	100	100

For occult blood, test results were:

	BLD	Predicate device				
		-	\pm	+1	+2	+3
Proposed device	+3					20
	+2				19	2
	+1		1	18	3	1
	\pm		43	4	1	
	-	220	7	1		
Total		220	51	23	23	23
% Agreement (exact match)		100	84	78	83	87
% Agreement (± 1 color block)		100	100	96	96	96

	BIL	Predicate device			
		—	+1	+2	+3
Proposed device	+3				13
	+2			19	
	+1	1	54	1	
	—	251	1		
Total		252	55	20	13
% Agreement (exact match)		99	98	95	100
% Agreement (± 1 color block)		100	100	100	100

	URO	Predicate device			
		Normal (0.2/1.0)	+1 (2.0)	+2 (4.0)	+3 (≥ 8.0)
Proposed device	+3				11
	+2			22	
	+1	1	51	2	
	Normal	249	4		
Total		250	55	24	11
% Agreement (exact match)		99	93	92	100
% Agreement (± 1 color block)		100	100	100	100

	PRO	Predicate device				
		—	\pm	+1	+2	+3
Proposed device	+3					15
	+2				16	
	+1		1	16	3	
	\pm		44	3	2	
	—	232	7	1		
Total		232	52	20	21	15
% Agreement (exact match)		100	85	80	76	100
% Agreement (± 1 color block)		100	100	95	90	100

	GLU	Predicate device (mg/dl)				
		—	± (100)	+1 (250)	+2 (500)	+3 (1000)
Proposed device (mg/dl)	+4 (1000)					15
	+3 (500)				14	1
	+2 (250)		2	15	1	
	+1 (100)		32	1		
	± (50)		4			
	—	255				
Total		255	38	16	15	16
% Agreement (exact match)		100	84	94	93	94
% Agreement (±1 color block)		100	100	100	100	100

	SG	Predicate device					
		1.005	1.010	1.015	1.020	1.025	1.030
Proposed device	1.030					1	39
	1.025				8	53	9
	1.020			20	78	13	
	1.015		5	34	9	2	
	1.010	4	43				
	1.005	15	7				
Total		19	55	54	95	69	48
% Agreement (exact match)		79	78	63	82	77	81
% Agreement (±1 color block)		100	100	100	100	97	100

	pH	Predicate device								
		5.0	5.5	6.0	6.5	7.0	7.5	8.0	8.5	9.0
Proposed device	9.0									4
	8.5								4	
	8.0							5	1	
	7.5						12	1		
	7.0				2	34	5			
	6.5				36	10				
	6.0			142	12					
	5.5	3	17	24						
	5.0	14	7	7						

Total	17	24	173	50	44	17	6	5	4
% Agreement (exact match)	82	71	82	72	72	71	83	80	100
% Agreement (± 1 color block)	100	100	96	100	100	100	100	100	100

5. Summary of Data

Uritest-50 with Uritest 10G VS. Clinitek 500 with Multistix 10SG

Analyte	% Agreement (within ± 1 color block)	% Agreement (exact match)	Analyte	% Agreement (within ± 1 color block)	% Agreement (exact match)
Leukocytes	100 (340/340)	94.4 (321/340)	Ketone	100 (340/340)	97.9 (333/340)
Nitrite	100 (340/340)	99.7 (339/340)	Urobilinogen	100 (340/340)	98.8 (336/340)
Bilirubin	100 (340/340)	98.2 (334/340)	Protein	99.1 (337/340)	95.3 (324/340)
Glucose	100 (340/340)	96.2 (327/340)	Specific Gravity	99.1 (337/340)	80.0 (272/340)
Blood	99.4 (338/340)	92.1 (313/340)	pH	99.4 (338/340)	78.5 (267/340)

Uritest-500B with Uritest 11G VS. Clinitek 500 with Multistix 10SG

Analyte	% Agreement (within ± 1 color block)	% Agreement (exact match)	Analyte	% Agreement (within ± 1 color block)	% Agreement (exact match)
Leukocytes	100 (340/340)	95.9 (326/340)	Ketone	100 (340/340)	98.5 (335/340)
Nitrite	100 (340/340)	100 (340/340)	Urobilinogen	100 (340/340)	97.9 (333/340)
Bilirubin	100 (340/340)	99.1 (337/340)	Protein	99.1 (337/340)	95.0 (323/340)
Glucose	100 (340/340)	97.4 (331/340)	Specific Gravity	99.4 (338/340)	77.1 (262/340)
Blood	99.1 (337/340)	94.1 (320/340)	pH	97.9 (333/340)	78.8 (268/340)

b. Matrix comparison:

Not applicable, this device is only used with urine.

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):*

4. Clinical cut-off:

Not applicable

5. Expected values/Reference range:

Reference ranges were drawn from literature:

Ketone: < 5 mg/dL

Nitrite: 0 mg/dL

Urobilinogen: 0.2-1.0 EU/dL

Bilirubin: 0 mg/dL

Protein: < 15 mg/dL

Glucose: < 50 mg/dL

Specific Gravity: 1.010-1.025

Blood: < 10 ery/micL

Ascorbic Acid: < 10 mg/dL

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2. "The Clinical Analysis of Urine Recent Period", The Science and Technology Publishing House, Yu Long Cong, Jun Long Ma, Editors; 1998; pp. 37-81, 96-97.
3. "Compendium – Urinalysis with Test Strips" Roche Diagnostic, Combur[®] Reagent Strips.'

N. Instrument Name:

Uritest-50 and Uritest 500B

O. System Descriptions:

1. Modes of Operation:

The Uritest 50 and Uritest-500B are automated urine analyzers using reflectance

spectroscopy for the semi-quantitative determination of pH, Specific Gravity, Protein, Glucose, Ketones, Urobilinogen, Bilirubin, Leukocyte esterase, Blood, Nitrite and Ascorbic Acid in urine samples. English is the default language.

2. Software:

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

Yes or No

3. Specimen Identification:

Numerical specimen identification information can be entered manually via a keypad on the analyzers, or it is available for use with a bar code scanner using the PS/2 port on the back of the instruments.

4. Specimen Sampling and Handling:

Uritest-50 analyzes one strip at a time. The user must wait for the completion of the strip before loading the next one.

Uritest 500B can analyze multiple strips. The user wets the test strip and places it on a sample tray. The analyzer pulls the strip inside to begin timing and analysis. The instrument prompts the user to wet another strip and put it on the tray thereby allowing multiple strips to be processed for analysis at one time.

5. Calibration:

Calibration is factory set, however a white calibration strip is used to check the remittance outputs of the LEDs in the read head. Labeling recommends that the user perform the calibration verification with the white strip after maintenance, with a new lot of strips, with a new bottle of strips, change of operator, or when there is a question with results.

6. Quality Control:

QC is analyzed like the patient samples. The QC data is not stored separately from patient data, however both analyzers can be connected to a computer via a RS 232 port. Labeling recommends two levels of quality control need to be assayed according to state, federal and local guidelines and 1) after using the check strip, 2) after maintenance or service 3) when starting a new lot number of test strips, 4) when starting a new bottle of test strips 5) changing operator, 6) when there are questionable results, 7) every 30 days to check the storage conditions of the strips.

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

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.