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

I Background Information:

A 510(k) Number

K232317

B Applicant

URIT Medical Electronic Co., Ltd.

C Proprietary and Established Names

UC-1800 Automatic Urine Analyzer, URIT 11FA Urine Reagent Strips, URIT 12FA Urine Reagent Strips

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
JIO	Class II	21 CFR 864.6550 - Occult blood test	HE - Hematology
JIL	Class II	21 CFR 862.1340 - Urinary Glucose (Nonquantitative) Test System	CH - Clinical Chemistry
JFY	Class II	21 CFR 862.1225 - Creatinine test system	CH - Clinical Chemistry
CDM	Class I	21 CFR 862.1785 - Urinary urobilinogen (nonquantitative) test system	CH - Clinical Chemistry
CEN	Class I	21 CFR 862.1550 - Urinary pH (nonquantitative) test system	CH - Clinical Chemistry
JIN	Class I	21 CFR 862.1435 - Ketones	CH - Clinical Chemistry

Product Code(s)	Classification	Regulation Section	Panel
		(nonquantitative) test system	
JJB	Class I	21 CFR 862.1115 - Urinary bilirubin and its conjugates (nonquantitative) test system	CH - Clinical Chemistry
JMT	Class I	21 CFR 862.1510 - Nitrite (nonquantitative) test system	CH - Clinical Chemistry
LJX	Class I	21 CFR 864.7675 - Leukocyte peroxidase test	HE - Hematology
JRE	Class I	21 CFR 862.2800 - Refractometer for clinical use	CH - Clinical Chemistry
JMA	Class I	21 CFR 862.1095 - Ascorbic acid test system	CH - Clinical Chemistry
JIR	Class I	21 CFR 862.1645 - Urinary protein or albumin (nonquantitative) test system	CH - Clinical Chemistry
KQO	Class I	21 CFR 862.2900 - Automated urinalysis system	CH - Clinical Chemistry

II Submission/Device Overview:

A Purpose for Submission:

New device

B Measurand:

Measurement of the following in urine samples: ascorbic acid, microalbumin, leukocytes, creatinine, ketone, urobilinogen, bilirubin, glucose, protein, specific gravity, blood, pH, nitrite, color and turbidity.

C Type of Test:

Qualitative and semi-quantitative urinalysis

III Intended Use/Indications for Use:

A Intended Use(s):
See Indications for Use below.

B Indication(s) for Use:
The UC-1800 Automatic Urine Analyzer is automated instrument which is intended for professional, in vitro diagnostic use only.

Depending on the reagent strips being used, the instruments perform semi-quantitative detection of the following analytes in urine: ascorbic acid, microalbumin, leukocytes, creatinine, ketone, urobilinogen, bilirubin, glucose, protein, specific gravity, blood and pH in urine and for qualitative determination of nitrite in urine. The urine hydrometer (optional) can determine the color and turbidity of urine. Test results may provide information regarding the status of carbohydrate metabolism, kidney and liver function, acid-base balance and bacteriuria.

The URIT 11FA urine reagent strips provide semi-quantitative tests for ascorbic acid, leukocytes, ketone, urobilinogen, bilirubin, glucose, protein, specific gravity, blood and pH in urine and for qualitative determination of nitrite in urine. The URIT 11FA urine reagent strips are for use with the UC-1800 Automatic Urine Analyzer and are for professional, 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.

The URIT 12FA urine reagent strips provide semi-quantitative tests for microalbumin, leukocytes, creatinine, ketone, urobilinogen, bilirubin, glucose, protein, specific gravity, blood and pH in urine and for qualitative determination of nitrite in urine. The URIT 12FA urine reagent strips are for use with the UC-1800 Automatic Urine Analyzer and are for professional, 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.

C Special Conditions for Use Statement(s):
Rx - For Prescription Use Only

URIT 11FA and 12FA Urine Reagent Strips are not to be read visually

The UC-1800 Automatic Urine Analyzer is for clinical laboratory use only, not for point-of-care use

D Special Instrument Requirements:

The UC-1800 Automatic Urine Analyzer

IV Device/System Characteristics:

A Device Description:

The UC-1800 Automatic Urine Analyzer is used together with the URIT 11FA and the URIT 12 FA test strips for semi-quantitative or qualitative detection of ascorbic acid, microalbumin, leukocytes, creatinine, ketone, urobilinogen, bilirubin, glucose, protein, specific gravity, blood, and pH in urine and for qualitative determination of nitrite in urine. The urine hydrometer (optional) can determine the specific gravity, color and turbidity of urine.

The URIT 11FA urine reagent strips provide semi-quantitative tests for ascorbic acid, leukocytes, ketone, urobilinogen, bilirubin, glucose, protein, specific gravity, blood and pH in urine and for qualitative determination of nitrite. The URIT 12FA urine reagent strips provide semi-quantitative tests for microalbumin, leukocytes, creatinine, ketone, urobilinogen, bilirubin, glucose, protein, specific gravity, blood and pH in urine and for qualitative determination of nitrite. Measured results are printed through either the built-in printer or an external printer.

B Principle of Operation:

Test strip measurement principle
The strips are used to determine the components to be measured in urine by dry chemistry methods together with the urine analyzer. Various components to be tested in urine can result in changes to the colors of corresponding reagent blocks on the Urine Reagent Strips. The depth of reaction color is proportional to the concentration of the corresponding component to be tested in the urine. Measurement of test strips is conducted by the analyzer using the reflective photoelectric colorimetry method using CIS (contact image sensor) image scanning analysis technology for detection.

URIT 11FA and 12FA Urine Reagent Strips
Ascorbic Acid (URIT 11FA only): Based on the principle of Tillman's Reagent, Ascorbic acid can reduce the dye from blue to red.

Nitrite: In this reaction, nitrate is reduced to nitrite by Gram-negative bacteria in the urine, the nitrite will react with arsanilic acid to form a diazonium compound, and the diazonium compound will be combined with naphthyl ethylenediamine dihydrochloride to show a pink color.

Microalbumin: Based on the dye-binding method, microalbumin can react with the dye to form a pink complex and produce a color change.

Leukocytes: Based on the esterase method, granulosa cytoplasm contains esterase, which can hydrolyze a 3-hydroxyindoxyl ester substrate, release phenol, and react with diazo reagent to generate purple-red compounds.

Creatinine: Based on the principle of displacement reaction, creatinine can displace the dye in the metal chloride-acid dye complex, and the color will change from green to yellow.

Ketone: Based on the principle of sodium nitro prussiate method, sodium nitroprusside can interact with ketone (acetoacetate) under alkaline conditions to become purple. Acetoacetate is particularly sensitive to this.

Urobilinogen: Based on the principle of the azo-binding method, urobilinogen is coupled with diazonium salt under strong acid conditions to form carmine pigment.

Bilirubin: Based on the principle of the azo-coupling method, 2,4-dichloroaniline diazonium salt can react specifically with bilirubin and produce different colors depending on the concentration of bilirubin.

Glucose: Based on the reaction principle of the glucose oxidase method, glucose oxidase can specifically oxidize β-D-glucose to generate glucuronic acid and hydrogen peroxide that will oxidize the indicator under the action of peroxidase and show a purple-red color.

Protein: Based on the principle of protein error method of dye binding, the protein can combine with the dye to form a complex that produces a color change. The response to albumin is more sensitive than that of globulin, hemoglobin, Bence-Jones, protein, and mucin.

Blood: Based on the principle of hemoglobin contact activity method, the decomposition of peroxides can be catalyzed through the peroxidase-like action of hemoglobin, thus oxidizing and coloring tetramethylbenzidine.

Specific Gravity: The test uses the polyelectrolyte method based on the principle of ion exchange between electrolytes in urine and polyelectrolytes. In the presence of cations, the polymer hydrogen ions will be released through exchange, and the color of bromothymol blue indicator will change from blue to blue-green and finally to yellow.

pH: The pH value within the range from 5.0 to 9.0 is measured by a Ph indicator.

UC-1800 Automatic Urine Analyzer

Measurement of test strips is performed by the reflectance photometry method. During the measurement, the reacted pads on strip (the calibration pad is not involved in reaction, just for reference) will change colors and absorb irradiated monochromatic light as a result of chemical reaction within 60 seconds. Then the optical mechanism will compare the amount of reflective light from each reacted pad with the reflective light of the calibration pad. The concentrations of analytes will be calculated by CPU and printed together with semi-quantitative symbols. The measuring system consists of a light source (LED) and a light receptor. The light from the light source shines on the reacted pads and the calibration pad on the strip. The absorbed and reflected light amounts vary with the color of the reagent pads. If the color is darker, more light is absorbed, and less light is reflected, and vice versa. (i.e., the degree of color development is proportional to the concentration of analyzes in urine).

Turbidity measurement principle: The turbidity module emits light through the sample and then detects how much light is scattered by the particles in the water at a 90° angle to the incident light.

Color measurement principle: The urine color can be detected by the professional color recognition sensor (filter).

C Instrument Description Information:

1. Instrument Name:

   UC-1800 Automatic Urine Analyzer

2. Specimen Identification:

   Urine identification can be performed manually or with analyzer barcode reader.

3. Specimen Sampling and Handling:

   The UC-1800 Automatic Urine Analyzer is characterized by fully automated operation. Samples can be labeled with a barcode, which is read with a barcode reader. The instrument automatically performs a series of operations: sample transmitting, sample aspirating, sample dropping, rinsing, strip sorting, strip feeding, color identifying, and measurement. Specimen handling recommendations are provided in the labeling.

4. Calibration:

   It is recommended to use the URIT specific gravity, turbidity, and color calibration products to calibrate the physical module every 4 weeks. A white calibration strip is used to check the remittance outputs of the LEDs in the read head. Labeling recommends that the user perform calibration verification with the white strip after maintenance, with a new lot of strips, with a new bottle of strips, when changing operators, or when questioning results.

5. Quality Control:

   Urinalysis controls are intended for the urine analyzer and matched urine reagent strips to monitor the quality of the urinalysis test. The following quality controls are recommended:
   Urinalysis Control NO.I: Negative control
   Urinalysis Control NO.II: Positive control
   Urinalysis Control NO.III: Positive control for Ascorbic Acid only
   Quality Control Solution TUR for turbidity
   Quality Control Solution COL for color

V Substantial Equivalence Information:

A Predicate Device Name(s):
Uritest 50 Urine Analyzer, Uritest -500B Urine Analyzer, Uritest 10G Urine Reagent Strips, Uritest 11G Urine Reagent Strips

B Predicate 510(k) Number(s):
K082811

C Comparison with Predicate(s):

Device & Predicate Device(s):	K232317	K082811
Device Trade Name	UC-1800 Automatic Urine Analyzer, URIT 11FA Urine Reagent Strips, URIT 12FA Urine Reagent Strips	Uritest-50 Urine Analyzer, Uritest-500B Urine Analyzer, Uritest 10G Urine Reagent Strips, Uritest 11G Urine Reagent Strips
General Device Characteristic Similarities		
Intended Use/Indications For Use	Semi-quantitative tests for ascorbic acid, leukocytes, ketone, urobilinogen, bilirubin, glucose, protein, specific gravity, blood and pH in urine	Same
Specimen Type	Human Urine	Same
Sampling Format	Strips	Same
Specimen ID enter	Manually enter or by bar code reader	Same
Analytes and Measuring Ranges	Ascorbic acid, Nitrite, Leukocyte, Ketone, Urobilinogen, Bilirubin, Glucose, Protein, Blood, Specific Gravity, PH	Same
Prescription Use	For prescription use only	Same
General Device Characteristic Differences		
Analytes	Microalbumin and Creatinine	N/A

VI Standards/Guidance Documents Referenced:

CLSI EP06 2nd Edition: Evaluation of Linearity of Quantitative Measurement Procedures

CLSI EP07 3rd Edition: Interference Testing in Clinical Chemistry

CLSI EP09c 3rd Edition: Measurement Procedure Comparison and Bias Estimation Using Patient Samples

CLSI EP17-A2: Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures

IEC 61010-1 Edition 3.1 2017-01: Consolidated Version: Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements

IEC 61326-2-6 Edition 3.0 2020-10: Electrical equipment for measurement control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment

IEC 61326-1 Edition 3.0 2020-10: Electrical equipment for measurement control and laboratory use - EMC requirements - Part 1: General requirements

IEC 60601-1 Edition 3.2 2020-08 Consolidated version: Medical electrical equipment – Part 1: General requirements for basic safety and essential performance

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

The Repeatability (With-in Run) Precision of the candidate device was evaluated using negative human urine samples and spiked urine samples for each analyte. Each sample was tested in 20 replicates across 3 instruments with the 3 lots of URIT 11FA Urine Reagent Strips and 3 lots of URIT 12FA Urine Reagent Strips (one lot of URIT 11FA and one lot of URIT 12FA test strips each instrument) for a total of 60 measurements at each concentration. The representative results are summarized in the tables below.

Summary of Repeatability (Within Run) Precision

Test	Expected Value					
Ascorbic acid (mg/dL)	-(0)	+-(10)	+1(25)	+2(50)	+3(100)	
Exact agreement	100% (60/60)	100% (60/60)	100% (60/60)	100% (60/60)	100% (60/60)	
± 1 color block	100% (60/60)	100% (60/60)	100% (60/60)	100% (60/60)	100% (60/60)	
Nitrite	- (Negative)	+ (Positive)				
Exact agreement	100% (60/60)	100% (60/60)				
± 1 color block	100% (60/60)	100% (60/60)				
Leukocyte (leu/μL)	-(0)	+-(15)	+1(70)	+2(125)	+3(500)	
Exact agreement	100% (60/60)	100% (60/60)	100% (60/60)	100% (60/60)	100% (60/60)	

Test	Expected Value					
± 1 color block	100% (60/60)	100% (60/60)	100% (60/60)	100% (60/60)	100% (60/60)	
Ketone (mg/dL)	-(0)	+-(5)	+1(15)	+2(40)	+3(80)	
Exact agreement	100% (60/60)	100% (60/60)	100% (60/60)	100% (60/60)	100% (60/60)	
± 1 color block	100% (60/60)	100% (60/60)	100% (60/60)	100% (60/60)	100% (60/60)	
Urobilinogen (EU/dL)	Normal		+1(2.0)	+2(4.0)	+3(8.0)	
Exact agreement	100% (60/60)		100% (60/60)	96.7% (58/60)	100% (60/60)	
± 1 color block	100% (60/60)		100% (60/60)	100% (60/60)	100% (60/60)	
Bilirubin (mg/dL)	-(0)		+1(0.5)	+2(2.0)	+3(6.0)	
Exact agreement	100% (60/60)		100% (60/60)	96.7% (58/60)	100% (60/60)	
± 1 color block	100% (60/60)		100% (60/60)	100% (60/60)	100% (60/60)	
Glucose (mg/dL)	-(0)	+-(50)	+1(100)	+2(250)	+3(500)	+4(1000)
Exact agreement	100% (60/60)	100% (60/60)	100% (60/60)	100% (60/60)	100% (60/60)	100% (60/60)
± 1 color block	100% (60/60)	100% (60/60)	100% (60/60)	100% (60/60)	100% (60/60)	100% (60/60)
Protein (mg/dL)	-(0)	+-(15)	+1(30)	+2(100)	+3(300)	
Exact agreement	100% (60/60)	100% (60/60)	93.3% (56/60)	100% (60/60)	100% (60/60)	
± 1 color block	100% (60/60)	100% (60/60)	100% (60/60)	100% (60/60)	100% (60/60)	
Specific Gravity	1.005	1.010	1.015	1.020	1.025	1.030
Exact agreement	100% (60/60)	96.7% (58/60)	100% (60/60)	100% (60/60)	100% (60/60)	100% (60/60)
± 1 color block	100% (60/60)	100% (60/60)	100% (60/60)	100% (60/60)	100% (60/60)	100% (60/60)
Blood (CELL/µL)	-(0)	+-(10)	+1(25)	+2(80)	+3(200)	
Exact agreement	100% (60/60)	100% (60/60)	98.3% (59/60)	100% (60/60)	100% (60/60)	
± 1 color block	100% (60/60)	100% (60/60)	100% (60/60)	100% (60/60)	100% (60/60)	
pH	5.0	5.5	6.0	6.5	7.0	7.5
Exact agreement	100% (60/60)	100% (60/60)	100% (60/60)	100% (60/60)	96.7% (58/60)	100% (60/60)
± 1 color block	100% (60/60)	100% (60/60)	100% (60/60)	100% (60/60)	100% (60/60)	100% (60/60)
pH	8.0	8.5	9.0			
Exact agreement	100% (60/60)	100% (60/60)	100% (60/60)			

Test	Expected Value					
± 1 color block	100% (60/60)	100% (60/60)	100% (60/60)			
Microalbumin	10mg/L	30mg/L	80mg/L	150mg/L		
Exact agreement	100% (60/60)	100% (60/60)	100% (60/60)	100% (60/60)		
± 1 color block	100% (60/60)	100% (60/60)	100% (60/60)	100% (60/60)		
Creatinine	10 mg/dL	50 mg/dL	100 mg/dL	200 mg/dL	300 mg/dL	
Exact agreement	100% (60/60)	100% (60/60)	100% (60/60)	100% (60/60)	100% (60/60)	
± 1 color block	100% (60/60)	100% (60/60)	100% (60/60)	100% (60/60)	100% (60/60)	

Summary of Repeatability (Within Run) Precision for Turbidity and Color

Test	Expected Value							
Turbidity	Clear	Micro turbid	Turbid	Very turbid				
Exact agreement	100% (60/60)	100% (60/60)	100% (60/60)	100% (60/60)				
± 1 Block	100% (60/60)	100% (60/60)	100% (60/60)	100% (60/60)				
Color	Colorless	Brown	Yellow	Red	Green	Orange	Blue	Purple
Exact agreement	100% (60/60)	100% (60/60)	100% (60/60)	100% (60/60)	100% (60/60)	100% (60/60)	100% (60/60)	100% (60/60)

The Reproducibility (Between-Run) Precision of the candidate device was evaluated by using negative human urine samples and spiked urine samples for each analyte. Each sample was tested for 20 days with 2 runs per day, 1 replicate per run using 3 lots of URIT 11FA Urine Reagent Strips and 3 lots of URIT 12FA Urine Reagent Strips on 3 instruments (one lot of URIT 11FA and one lot of URIT 12FA test strips each instrument) in 3 sites (one instrument per site) for a total of 120 measurements at each concentration. The representative results are summarized in the tables below.

Summary of Reproducibility (Between-Run) Precision

Test	Expected Value					
Ascorbic acid (mg/dL)	-(0)	+-(10)	+1(25)	+2(50)	+3(100)	
Exact agreement	100% (120/120)	100% (120/120)	100% (120/120)	94.2% (113/120)	100% (120/120)	
± 1 color block	100% (120/120)	100% (120/120)	100% (120/120)	100% (120/120)	100% (120/120)	

Test	Expected Value					
Nitrite	- (Negative)	+ (Positive)				
Exact agreement	100% (120/120)	100% (120/120)				
± 1 color block	100% (120/120)	100% (120/120)				
Leukocyte (leu/µL)	-(0)	+-(15)	+1(70)	+2(125)	+3(500)	
Exact agreement	100% (120/120)	100% (120/120)	100% (120/120)	100% (120/120)	100% (120/120)	
± 1 color block	100% (120/120)	100% (120/120)	100% (120/120)	100% (120/120)	100% (120/120)	
Ketone (mg/dL)	-(0)	+-(5)	+1(15)	+2(40)	+3(80)	
Exact agreement	100% (120/120)	100% (120/120)	100% (120/120)	100% (120/120)	100% (120/120)	
± 1 color block	100% (120/120)	100% (120/120)	100% (120/120)	100% (120/120)	100% (120/120)	
Urobilinogen (EU/dL)	Normal		+1(2.0)	+2(4.0)	+3(8.0)	
Exact agreement	100% (120/120)		100% (120/120)	98.3% (118/120)	100% (120/120)	
± 1 color block	100% (120/120)		100% (120/120)	100% (120/120)	100% (120/120)	
Bilirubin (mg/dL)	-(0)		+1(0.5)	+2(2.0)	+3(6.0)	
Exact agreement	100% (120/120)		100% (120/120)	100% (120/120)	100% (120/120)	
± 1 color block	100% (120/120)		100% (120/120)	100% (120/120)	100% (120/120)	
Glucose(mg/dL)	-(0)	+-(50)	+1(100)	+2(250)	+3(500)	+4(1000)
Exact agreement	100% (120/120)	100% (120/120)	100% (120/120)	100% (120/120)	100% (120/120)	100% (120/120)
± 1 color block	100% (120/120)	100% (120/120)	100% (120/120)	100% (120/120)	100% (120/120)	100% (120/120)
Test	Expected Value					
Protein (mg/dL)	-(0)	+-(15)	+1(30)	+2(100)	+3(300)	
Exact agreement	100% (120/120)	100% (120/120)	100% (120/120)	99.2% (119/120)	100% (120/120)	
± 1 color block	100% (120/120)	100% (120/120)	100% (120/120)	100% (120/120)	100% (120/120)	
Specific Gravity	1.005	1.010	1.015	1.020	1.025	1.030
Exact agreement	100% (120/120)	100% (120/120)	100% (120/120)	100% (120/120)	100% (120/120)	100% (120/120)
± 1 color block	100% (120/120)	100% (120/120)	100% (120/120)	100% (120/120)	100% (120/120)	100% (120/120)
Blood (CELL/µL)	-(0)	+-(10)	+1(25)	+2(80)	+3(200)	

Test	Expected Value					
Exact agreement	100% (120/120)	100% (120/120)	100% (120/120)	95% (114/120)	97.5% (117/120)	
± 1 color block	100% (120/120)	100% (120/120)	100% (120/120)	100% (120/120)	100% (120/120)	
pH	5.0	5.5	6.0	6.5	7.0	7.5
Exact agreement	100% (120/120)	100% (120/120)	100% (120/120)	100% (120/120)	99.2% (119/120)	100% (120/120)
± 1 color block	100% (120/120)	100% (120/120)	100% (120/120)	100% (120/120)	100% (120/120)	100% (120/120)
pH	8.0	8.5	9.0			
Exact agreement	100% (120/120)	100% (120/120)	100% (120/120)			
± 1 color block	100% (120/120)	100% (120/120)	100% (120/120)			
Microalbumin	10mg/L	30mg/L	80mg/L	150mg/L		
Exact agreement	100% (120/120)	100% (120/120)	100% (120/120)	100% (120/120)		
± 1 color block	100% (120/120)	100% (120/120)	100% (120/120)	100% (120/120)		
Creatinine	10 mg/dL	50 mg/dL	100 mg/dL	200 mg/dL	300 mg/dL	
Exact agreement	100% (120/120)	100% (120/120)	100% (120/120)	100% (120/120)	100% (120/120)	
± 1 color block	100% (120/120)	100% (120/120)	100% (120/120)	100% (120/120)	100% (120/120)	

Summary of Repeatability (Between-Run) Precision for Turbidity and Color

Test	Expected Value							
Turbidity	Clear	Micro turbid	Turbid	Very turbid				
Exact agreement	100% (120/120)	100% (120/120)	100% (120/120)	100% (120/120)				
± 1 Block	100% (120/120)	100% (120/120)	100% (120/120)	100% (120/120)				
Color	Colorless	Brown	Yellow	Red	Green	Orange	Blue	Purple
Exact agreement	100% (120/120)	100% (120/120)	100% (120/120)	100% (120/120)	100% (120/120)	100% (120/120)	100% (120/120)	100% (120/120)

2. Linearity:

A study was conducted to evaluate the assay reportable range for each analyte of the candidate device. The assay reportable range was evaluated by measuring samples containing known concentrations of all measurement blocks of all analytes. The results are summarized in the tables below.

Summary of Linearity of URIT 11/12FA Urine Reagent Strips - Common Analytes

Analyte	Qualitative Rank	Semi-Quantitative Rank	Concentration/Level Tested	Agreement at same block
Leukocyte	-	0	0 leu/mcL	100% (63/63)
	+/-	15	15 leu/mcL	100% (63/63)
	+1	70	70 leu/mcL	100% (63/63)
	+2	125	125 leu/mcL	100% (63/63)
	+3	500	500 leu/mcL	100% (63/63)
Ketones	-	0	0 mg/dL	100% (63/63)
	+/-	5	5 mg/dL	100% (63/63)
	+1	15	15 mg/dL	100% (63/63)
	+2	40	40 mg/dL	100% (63/63)
	+3	80	80 mg/dL	100% (63/63)
Urobilinogen	Normal	Normal	Normal	100% (63/63)
	+1	2.0	2.0 mg/dL	100% (63/63)
	+2	4.0	4.0 mg/dL	100% (63/63)
	+3	8.0	8.0 mg/dL	100% (63/63)
Bilirubin	-	0	0 mg/dL	100% (63/63)
	+1	0.5	0.5 mg/dL	100% (63/63)
	+2	2.0	2.0 mg/dL	100% (63/63)
	+3	6.0	6.0 mg/dL	100% (63/63)
Glucose	-	0	0 mg/dL	100% (63/63)
	+/-	50	50 mg/dL	100% (63/63)
	+1	100	100 mg/dL	100% (63/63)

Analyte	Qualitative Rank	Semi-Quantitative Rank	Concentration/Level Tested	Agreement at same block
	+2	250	250 mg/dL	100% (63/63)
	+3	500	500 mg/dL	100% (63/63)
	+4	1000	100 mg/dL	100% (63/63)
Protein	-	0	0 mg/dL	100% (63/63)
	+/-	15	15 mg/dL	100% (63/63)
	+1	30	30 mg/dL	100% (63/63)
	+2	100	100 mg/dL	100% (63/63)
	+3	300	300 mg/dL	100% (63/63)
Blood	-	0	0 ery/mcL	100% (63/63)
	+/-	10	10 ery/mcL	100% (63/63)
	+1	25	25 ery/mcL	100% (63/63)
	+2	80	80 ery/mcL	100% (63/63)
	+3	200	200 ery/mcL	100% (63/63)
Specific Gravity	N/A	1.005	1.005	100% (63/63)
		1.010	1.010	100% (63/63)
		1.015	1.015	100% (63/63)
		1.020	1.020	100% (63/63)
		1.025	1.025	100% (63/63)
		1.030	1.030	100% (63/63)
pH	N/A	5.0	5.0	100% (63/63)
		5.5	5.5	100% (63/63)
		6.0	6.0	100% (63/63)

Analyte	Qualitative Rank	Semi-Quantitative Rank	Concentration/Level Tested	Agreement at same block
		6.5	6.5	100% (63/63)
		7.0	7.0	100% (63/63)
		7.5	7.5	100% (63/63)
		8.0	8.0	100% (63/63)
		8.5	8.5	100% (63/63)
		9.0	9.0	100% (63/63)

Summary of URIT 11FA Urine Reagent Strips - Ascorbic acid

Analyte	Qualitative Rank	Semi-Quantitative Rank	Concentration/Level Tested	Agreement at same block
Ascorbic acid	-	0	0 mg/dL	100% (63/63)
	+1	10	10 mg/dL	100% (63/63)
	+2	25	25 mg/dL	100% (63/63)
	+3	50	50 mg/dL	100% (63/63)
	+4	100	100 mg/dL	100% (63/63)

Summary of URIT 12FA Urine Reagent Strips - Microalbumin and Creatinine

Analyte	Semi-Quantitative Rank	Concentration/Level Tested	Agreement at same block
Microalbumin	10	0 mg/dL	100% (63/63)
	30	10 mg/dL	100% (63/63)
	80	25 mg/dL	100% (63/63)
	150	50 mg/dL	100% (63/63)
Creatinine	10	10 mg/dL	100% (63/63)
	50	50 mg/dL	100% (63/63)
	100	100 mg/dL	100% (63/63)
	200	200 mg/dL	100% (63/63)
	300	300 mg/dL	100% (63/63)

The results of the assay reportable range studies support the following measurement ranges for the candidate device:

Analyte	URIT Urine Reagent Strips	
	11 FA	12FA
Ascorbic acid	0, 10, 25, 50, 100 mg/dL	N/A
	-, +/-, +1, +2, +3	
Microalbumin	N/A	10, 30, 80, 150 mg/L
Leukocytes	0, 15, 70, 125, 500 leu/mcL	
	-, +/-, +1, +2, +3	
Creatinine	N/A	10, 50, 100, 200, 300 mg/dL
Ketone	0, 5, 15, 40, 80 mg/dL	
	-, +/-, +1, +2, +3	
Urobilinogen	Normal, 2.0, 4.0, 8.0 EU/dL	
	Normal, +1, +2, +3	
Bilirubin	0, 0.5, 2.0, 6.0 mg/dL	
	-, +1, +2, +3	
Glucose	0, 50, 100, 250, 500, 1000 mg/dL	
	-, +/-, +1, +2, +3, +4	
Protein	0, 15, 30, 100, 300 mg/dL	
	-, +/-, +1, +2, +3	
Blood	0, 10, 25, 80, 200 ery/mcL	
	-, +/-, +1, +2, +3	
Specific Gravity	1.005, 1.010, 1.015, 1.020, 1.025, 1.030	
pH	5.0, 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0	

3. Analytical Specificity/Interference:

Exogenous and Endogenous Interference
Analytical specificity studies were conducted to evaluate interfering effects of exogenous and endogenous substances on the candidate device. Negative urine samples and low positive samples were spiked with potential interfering substances at various interferent concentrations. Each sample pair (test sample and control sample) was analyzed in replicates of 5 on two UC-1800 Automatic Urine Analyzers with two lots of URIT 11FA and 12FA reagent strips respectively (2 lots of each reagent strip on each analyzer). Results are summarized in the tables below.

The following substances show no interference at tested concentrations:

Substance	Highest Concentration with No Interference
Cefoxitin	1200 mg/dL
Ofloxacin	90 mg/dL
Phenazopyridine	30 mg/dL
Salicylic acid	600 mg/dL
Tetracycline	50 mg/dL
Hydroxybutyrate dehydrogenase	450 mg/dL
Protein*	500 mg/dL
Lactose	10mg/dL

Substance	Highest Concentration with No Interference
Leukocyte**	2500leu/uL
Potassium chloride	1500 mg/dL
Citric acid	150 mg/dL
Creatine	10mg/dL
Fructose	100mg/dL
Galactose	80 mg/dL
Oxalic acid	70mg/dL
Vitamin B	10mg/dL
Sodium acetate	2.25mg/dL
Sodium chloride	5500mg/dL
Sodium nitrate	10mg/dL
Theophylline	100 mg/dL

* This non-interference claim does not apply to protein .

**This non-interference claim does not apply to leukocytes

The following substances that cause interference are listed in the table below.

Analyte	Substance	Concentration limit with no significant interference (mg/dL)	Interference concentration (mg/dL)	Effect when above the concentration limit
Leukocyte	Urobilinogen	25	50	From - to +- (False Positive)
			75	From +- to 1 (Elevated Positive Result)
			150	From +- to 2 (Elevated Positive Result)
			150	From - to 1 (False Positive)
	Amoxicillin	700	1050	From +- to - (False Negative)
	Ibuprofen	125	187.5	From +- to - (False Negative)
	Methylamine + Methylene Blue	200 + 35	300 + 52.5	From - to +- (False Positive)
		200 + 35	300 + 52.5	From +- to 1 (Elevated Positive Result)
	Bilirubin	60	80	From - to +- (False Positive)
	Glucose	1500	1666.7	From +- to - (False Negative)
Ketones	Sodium Bicarbonate	375	750	From +- to - (False Negative)
	Glycine	225	337.5	From +- to - (False Negative)
	Sodium Phosphate	250	375	From +- to - (False Negative)
	Methyldopa	50	100	From - to +- (False Positive)
			150	From +- to 1 (Elevated Positive Result)
	Methylamine + Methylene Blue	100 + 17.5	200 + 35	From +- to - (False Negative)

Analyte	Substance	Concentration limit with no significant interference (mg/dL)	Interference concentration (mg/dL)	Effect when above the concentration limit
	Acetylcysteine	3.3	5	From - to +- (False Positive)
			5	From +- to 1 (Elevated Positive Result)
	Ammonium Chloride	1250	1875	From +- to - (False Negative)
	Bilirubin	60	80	From +- to - (False Negative)
	Creatinine	1125	1500	From - to +- (False Positive)
Urobilinogen	Gabapentin	15	22.5	From 1+ to Normal (False Negative)
	Methylamine + Methylene Blue	66.7 + 11.7	200 + 35	From Normal to 1+ (False Positive)
			100 + 17.5	From 1+ to 2+ (Elevated Positive Result)
	Bilirubin	40	60	From 1+ to 2+ (Elevated Positive Result)
	Nitrite	0.8	1.7	From 1+ to Normal (False Negative)
Bilirubin	Urobilinogen	12.5	25	From - to 1+ (False Positive)
			25	From 1+ to 2+ (Elevated Positive Result)
			50	From - to 2+ (False Positive)
	Ascorbic Acid	150	200	From 1+ to - (False Negative)
	Methylamine + Methylene Blue	200 + 35	300 + 52.5	From 1+ to - (False Negative)
	Nitrite	5	10	From 1+ to - (False Negative)
Glucose	Lithium Acetoacetate	80	125	From +- to - (False Negative)
	Peroxide	5%	7.50%	From - to +- (False Positive)
				From +- to 1+ (Elevated Positive Result)
	Ascorbic Acid	50	100	From +- to - (False Negative)
	Levodopa	10.8	21.7	From +- to - (False Negative)
	Methylamine + Methylene Blue	100 + 17.5	200 + 35	From +- to - (False Negative)
	Bilirubin	40	60	From +- to - (False Negative)
	Urea	10,050	15,025	From +- to - (False Negative)
Protein	Quaternary Ammonium	50	100	From - to +- (False Positive)
				From +- to 1 (Elevated Positive Result)
			150	From - to 1+ (False Positive)

Analyte	Substance	Concentration limit with no significant interference (mg/dL)	Interference concentration (mg/dL)	Effect when above the concentration limit
				From +- to 2 (Elevated Positive Result)
	Sodium Bicarbonate	750	1125	From +- to 1 (Elevated Positive Result)
	Amoxicillin	700	1050	From +- to - (False Negative)
	Gabapentin	7.5	15	From +- to 1+ (Elevated Positve Reuslt)
	Ibuprofen	62.5	125	From +- to - (False Negative)
	Methylamine + Methylene Blue	66.7 + 11.7	100 + 17.5	From +- to 1+ (Elevated Positive Result)
			200 + 35	From - to +- (False Positive)
	Ammonium Chloride	625	1250	From +- to - (False Negative)
	Bilirubin	40	60	From - to +- (False Positive)
	Calcium Chloride	150	225	From +- to - (False Negative)
	Creatinine	375	750	From +- to 1+ (Elevated Positive Result)
			1500	From - to +-/1+ (False Positive and Elevated Positive Result)
	HGB	1250	2500	From +- to 1+ (Elevated Positive Result)
			3750	From - to +-/1+ (False Positive and Elevated Positive Result)
	Urea	10,050	15,025	From +- to 1+ (Elevated Positive Result)
Blood	Peroxidase	5	10	From - to +- (False Positive)
				From +- to 1+ (Elevated Positive Result)
	Sodium Bicarbonate	375	750	From +- to - (False Negative)
	Glycine	112.5	225	From +- to 1+ (Elevated Positive Result)
	Ascorbic Acid	50	100	From +- to - (False Negative)
	Biotin	2500	3750	From - to +- (False Positive)
	Furosemide	50	100	From +- to - (False Negative)
	Ibuprofen	187.5	250	From +- to - (False Negative)
	Levodopa	10.8	21.7	From +- to - (False Negative)
	Methyldopa	16.7	33.3	From - to +- (False Positive)
			150	From +- to 1+ (Elevated Positive Result)
		66.7 + 11.7	100 + 17.5	From - to +- (False Positive)

Analyte	Substance	Concentration limit with no significant interference (mg/dL)	Interference concentration (mg/dL)	Effect when above the concentration limit
	Methylamine + Methylene Blue			From +- to 1+ (Elevated Positive Result)
Specific Gravity	Salicylic Acid	300	450	From 1.010 to 1.020 (Result Rise)
			600	From 1.010 to 1.030 (Result Rise)
	Uric Acid	116.25	155	From 1.015 to 1.025 (Result Rise)
	Sodium Bicarbonate	1125	1500	From 1.020 to 1.005 (Result Reduction)
Nitrite	Urobilinogen	12.5	25	From - to + (False Positive)
	Sodium Bicarbonate	750	1125	From + to - (False Negative)
	Ascorbic Acid	50	100	From + to - (False Negative)
	Methylamine + Methylene Blue	200 + 35	300 + 52.5	From - to + (False Positive)
	Bilirubin	60	80	From + to - (False Negative)
	Creatinine	750	1125	From + to - (False Negative)
Ascorbic Acid	Sodium Thiosulfate	10	15	From - to +- (False Positive)
				From +- to 1+ (Elevated Positive Result)
	Cysteine	10	15	From - to +- (False Positive)
				From +- to 1+ (Elevated Positive Result)
	Sodium Phosphate	250	375	From +- to 1+ (Elevated Positive Result)
	Levodopa	5.4	10.8	From +- to 1+ (Elevated Positive Result)
	Acetylcysteine	10	15	From +- to 1+ (Elevated Positive Result)
	Ammonium Chloride	1875	2500	From +- to 1+ (Elevated Positive Result)
Microalbumin	Quaternary Ammonium	50	100	From 10 mg/L to 30 mg/L (False Positive)
				From 30 mg/L to 80 mg/L (Elevated Positive Result)
	Blood	0.0375%	0.05%	From 10 mg/L to 30 mg/L (False Positive)
				From 30 mg/L to 80 mg/L (Elevated Positive Result)

Analyte	Substance	Concentration limit with no significant interference (mg/dL)	Interference concentration (mg/dL)	Effect when above the concentration limit
	Human IgG	41.67	83.33	From 10 mg/L to 30 mg/L (False Positive)
				From 30 mg/L to 80 mg/L (Elevated Positive Result)
			375	From 10 mg/L to 80 mg/L (False Positive)
				From 30 mg/L to 150 mg/L (Elevated Positive Result)
	Ascorbic Acid	200	300	From 30 mg/L to 10 mg/L (False Negative)
	Gabapentin	7.5	15	From 30 mg/L to 80 mg/L (Elevated Positive Result)
			30	From 10 mg/L to 30 mg/L (False Positive)
	Methylamine + Methylene Blue	66.7 + 11.7	100 + 17.5	From 10 mg/L to 30 mg/L (False Positive)
			200 + 35	From 30 mg/L to 80 mg/L (Elevated Positive Result)
	Ammonium Chloride	625	1250	From 30 mg/L to 10 mg/L (False Negative)
	Creatinine	600	750	From 30 mg/L to 80 mg/L (Elevated Positive Result)
			1500	From 10 mg/L to 30 mg/L (False Positive)
	HGB	83	208	From 30 mg/L to 80 mg/L (Elevated Positive Result)
			830	From 10 mg/L to 30 mg/L (False Positive)
Creatinine	Acetaminophen	225	300	From 50 mg/dL to 100 mg/dL (Elevated Positive Result)
	Biotin	830	1250	From 50 mg/dL to 100 mg/dL (Elevated Positive Result)
	Furosemide	100	150	From 50 mg/dL to 100 mg/dL (Elevated Positive Result)
	Gabapentin	15	22.5	From 50 mg/dL to 100 mg/dL (Elevated Positive Result)
	Gentamicin Sulphate	20	30	From 50 mg/dL to 10 mg/dL (False Negative)
	Acetylcysteine	3.3	5	From 50 mg/dL to 100 mg/dL (Elevated Positive Result)
			200	From 10 mg/dL to 50 mg/dL (False Positive)

Analyte	Substance	Concentration limit with no significant interference (mg/dL)	Interference concentration (mg/dL)	Effect when above the concentration limit
	Ammonium Chloride	100	104.2	From 50 mg/dL to 10 mg/dL (False Negative)

To address the interference of levodopa on the test for blood, the following interference limitation is included in the labeling and will be reported in the test report: Levodopa can interfere with the detection of red blood cells leading to a false negative result.

Interference effect of urine pH

Studies were conducted to assess the effect of urine pH on the test results. For all test strip analytes, except leukocytes and specific gravity, there was no interference from pH across a range of 4.5 to 8.5. Interference effects of urine pH on leukocytes and specific gravity are summarized in the table below.

Analyte	URIT 11/12 FA Urine Reagent Strips	
	No interference	Interference condition
Leukocytes	pH > 5.5	pH=4.5，From +- to - (False Negative)
Specific Gravity	5.5-7.5	pH=4.5，From 1.015 to 1.025 (False Positive)
		pH=4.5，From 1.020 to 1.030 (False Positive)
		pH≥8.5，From 1.015 to 1.005 (False Negative)
		pH≥8.5，From 1.020 to 1.010 (False Negative)

Interference effect of urine color

The candidate device includes a correction function for urine colors. The results of the studies demonstrated that the colors red, orange, brown, yellow, green, blue, and purple do not significantly impact the results for the analytes on the URIT 11FA and 12 FA test strips since all results were within +/- 1 color block when testing colored urine for these parameters on the URIT 11FA and 12FA Urine Reagent Strips.

Interference effect of urine Specific Gravity

Studies were conducted to assess the effect of urine specific gravity on the test results. A negative urine sample was prepared using sodium chloride to adjust the specific gravity to 1.005, 1.010, 1.015, 1.020, 1.025, 1.030, 1.035, 1.040, 1.045, and 1.050, respectively. For all test strip analytes, except leukocytes, there was no interference from specific gravity across a range of 1.005 to 1.050. For leukocytes, false negative results were found at urine specific gravity values higher than 1.040.

Analyte	URIT 11/12 FA Urine Reagent Strips	
	No interference	Interference effect
Leukocytes	SG < 1.035	SG ≥1.040 ， From +- to- (false negative)

4. Assay Reportable Range:

The reportable ranges claimed by the sponsor for the candidate device are summarized in the table below:

Analyte	URIT Urine Reagent Strips	
	11 FA	12FA
Ascorbic acid	0, 10, 25, 50, 100 mg/dL	N/A
	-, +/-, +1, +2, +3	N/A
Microalbumin	N/A	10, 30, 80, 150 mg/L
Leukocytes	0, 15, 70, 125, 500 leu/mcL	
	-, +/-, +1, +2, +3	
Creatinine	N/A	10, 50, 100, 200, 300 mg/dL
Ketone	0, 5, 15, 40, 80 mg/dL	
	-, +/-, +1, +2, +3	
Urobilinogen	Normal, 2.0, 4.0, 8.0 EU/dL	
	Normal, +1, +2, +3	
Bilirubin	0, 0.5, 2.0, 6.0 mg/dL	
	-, +1, +2, +3	
Glucose	0, 50, 100, 250, 500, 1000 mg/dL	
	-, +/-, +1, +2, +3, +4	
Protein	0, 15, 30, 100, 300 mg/dL	
	-, +/-, +1, +2, +3	
Blood	0, 10, 25, 80, 200 ery/mcL	
	-, +/-, +1, +2, +3	
Specific Gravity	1.005, 1.010, 1.015, 1.020, 1.025, 1.030	
pH	5.0, 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0	

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

Traceability
The sponsor provided information to support the traceability of the candidate device.

6. Detection Limit:

Analytical sensitivity
The detection limit study defines the measurement results with analytical sensitivity of 90% as the positive minimum analyte concentration, i.e., the cutoff for switching from negative to

positive. Each analyte was added to a negative urine sample to prepare five different concentrations. Each concentration was tested on three UC-1800 analyzers with three lots of test strips. Each lot of test strip was tested 20 times on each analyzer. The results are summarized below:

Analyte	URIT Urine Reagent Strips	
	11FA	12FA
Ascorbic acid	8~10 mg/dL	N/A
Nitrite	0.1-0.2mg/dL	
Microalbumin	N/A	20-30 mg/L
Leukocyte	10~15 leu/mcL	
Creatinine	N/A	25~50 mg/dL
Ketone	4~5 mg/dL	
Urobilinogen	1~2 EU/dL	
Bilirubin	0.4~0.5 mg/dL	
Glucose	40~50 mg/dL	
Protein	10~15 mg/dL	
Blood	5~10 ery/mcL	

Analytical sensitivity is not applicable for both strips in the detection of pH and Specific Gravity.

Study 2 – Measurement block cut-off:

A cut-off study was conducted on the candidate device to determine the cut-off concentration between each semi-quantitative block of the reagent strip. The cut-off concentration is defined as the minimum sample concentration at which a test result of ≥55% relative to the transition from the block is considered positive. Each testing analyte was added to the negative urine sample to have five concentrations exceeding the expected cut-off concentration. Three lots of URIT 11FA and 12FA urine reagent strips were tested in 20 replicates at each concentration level on three UC-1800 urine analyzers.

The cut-off concentration between each measurement block is summarized in the tables below.

Glucose			
Block Output	**Cut-off, mg/dL**	**% Positive (11FA Strips)**	**% Positive (12FA Strips)**
100 (1+)	75	86	73
250 (2+)	165	77	74
500 (3+)	360	66	76
1000 (4+)	735	71	74

Blood			
Block Output	**Cut-off, ery/µL**	**% Positive (11FA Strips)**	**% Positive (12FA Strips)**
25 (1+)	16	79	77
80 (2+)	65	77	79
200 (3+)	130	79	71

Urobilinogen			
Block Output	**Cut-off, EU/dL**	**% Positive (11FA Strips)**	**% Positive (12FA Strips)**
4 (2+)	1.8	81	77
8 (3+)	4.5	71	74

Ketones			
Block Output	**Cut-off, mg/dL**	**% Positive (11FA Strips)**	**% Positive (12FA Strips)**
15 (2+)	8	82	74
40 (3+)	25	82	76
80 (4+)	63	72	71

Protein			
Block Output	**Cut-off, mg/dL**	**% Positive (11FA Strips)**	**% Positive (12FA Strips)**
30 (1+)	21	77	83
100 (2+)	65	75	70
300 (3+)	180	79	70

Bilirubin			
Block Output	**Cut-off, mg/dL**	**% Positive (11FA Strips)**	**% Positive (12FA Strips)**
2 (2+)	1.3	88	78
6 (3+)	3	79	73

Leukocyte			
Block Output	**Cut-off, leu/µL**	**% Positive (11FA Strips)**	**% Positive (12FA Strips)**
70 (1+)	38	92	74
125 (2+)	88	85	64
500 (3+)	337	77	69

pH			
Block Output	**Cut-off**	**% Positive (11FA Strips)**	**% Positive (12FA Strips)**
5.5	5.2	83	73
6.0	5.8	86	79
6.5	6.3	82	77
7.0	6.7	81	78
7.5	7.3	76	82
8.0	7.8	82	76
8.5	8.2	72	94
9.0	8.8	68	77

Ascorbic Acid			
Block Output	**Cut-off, mg/dL**	**% Positive (11FA Strips)**	**% Positive (12FA Strips)**
25 (1+)	12	76	N/A
50 (2+)	32	89	
100 (3+)	72	66	

Creatinine			
Block Output	**Cut-off, mg/dL**	**% Positive (11FA Strips)**	**% Positive (12FA Strips)**
100	6.5	N/A	77
200	12.5		75
300	21		79

Microalbumin			
Block Output	**Cut-off, mg/L**	**% Positive (11FA Strips)**	**% Positive (12FA Strips)**
80	80	N/A	88
150	150		79

7. Assay Cut-Off:

   Not applicable.

8. Accuracy (Instrument):

   See Method Comparison.

9. Carry-Over:

   The carryover of the candidate device was evaluated by alternately testing high-concentration samples and low-concentration samples, in the sequence of high, low, high, low, high, low, high, low, high and low. For all analytes, all negative/normal samples read as negative/normal, therefore no significant carryover found in the study.

B Comparison Studies:

1. Method Comparison with Predicate Device:

The accuracy of the test system was assessed by a method comparison study for agreement with comparator devices for each analyte/parameter on candidate device.

A total of 1000 clinical urine samples were tested for the comparison study with the comparator device URITEST-500B Urine Analyzer (K082811), and representative results are summarized in the tables below.

Representative results of URIT 11FA and 12 FA Reagent Strips

Ascorbic acid (N=1000) (mg/dL)		URIT UC-1800 Automatic Urine Analyzer (11FA test strips)				
		-(0)	+-(10)	+1(25)	+2(50)	+3(100)
Predicate device (K082811) Uritest-500B urine analyzer (11G test strip)	- (0)	716	0	0	0	0
	+-(10)	0	95	0	0	0
	+1(25)	0	0	98	1	0
	+2(50)	0	0	1	40	1
	+3(100)	0	0	0	0	48
Total		716	95	99	41	49
Exact agreement %		100%	100%	99.00%	97.60%	98.00%
Agreement ± 1 block %		100%	100%	100%	100%	100%

Leukocyte (N=1000) (Leu/mcL)		URIT UC-1800 Automatic Urine Analyzer (11FA test strips)				
		-(0)	+-(15)	+1(70)	+2(125)	+3(500)
Predicate device (K082811) Uritest-500B urine analyzer (11G test strip)	-(0)	532	4	0	0	0
	+-(15)	3	205	1	0	0
	+1(70)	0	0	107	2	0
	+2(125)	0	0	1	69	0
	+3(500)	0	0	0	1	75
Total		535	209	109	72	75
Exact agreement %		99.40%	98.10%	98.20%	95.80%	100%
Agreement ± 1 block %		100%	100%	100%	100%	100%

Ketone (N=1000) (mg/dL)		URIT UC-1800 Automatic Urine Analyzer (11FA test strips)				
		-(0)	+-(5)	+1(15)	+2(40)	+3(80)
Predicate device (K082811) Uritest-500B urine analyzer (11G test strip)	-(0)	828	0	0	0	0
	+-(5)	1	45	1	0	0
	+1(15)	0	0	37	1	0
	+2(40)	0	0	0	37	1
	+3(80)	0	0	0	0	49
Total		829	45	38	38	50
Exact agreement %		99.90 %	100%	97.40%	97.40%	98.00 %
Agreement ± 1 block %		100%	100%	100%	100%	100%

Nitrite (N=1000)		URIT UC-1800 Automatic Urine Analyzer (11FA test strips)	
		+	-
Predicate device (K082811) Uritest-500B urine analyzer (11G test strip)	+	216	3
	-	3	778
Total		219	781
Complete agreement rate		98.60%	99.60%
		95% confidence interval	
Overall agreement rate OPA	99.40%	98.70%	99.72%
Positive percentage agreement rate PPA	98.63%	96.05%	99.53%
Negative percentage agreement rate NPA	99.62%	98.88%	99.87%

Urobilinogen(N=1000) (EU/dL)		URIT UC-1800 Automatic Urine Analyzer (11FA test strips)			
		Normal	+1(2.0)	+2(4.0)	+3(8.0)
Predicate device (K082811) Uritest-500B urine analyzer (11G test strip)	Normal	900	1	0	0
	+1(2.0)	1	42	1	0
	+2(4.0)	0	0	29	0
	+3(8.0)	0	0	0	26
Total		901	43	30	26
Exact agreement %		99.90%	97.70%	96.70%	100%
Agreement ± 1 block %		100%	100%	100%	100%

Bilirubin(N=1000) (mg/dL)		URIT UC-1800 Automatic Urine Analyzer (11FA test strips)			
		-(0)	+1(0.5)	+2(2.0)	+3(6.0)
Predicate device (K082811) Uritest-500B urine analyzer (11G test strip)	-(0)	931	0	0	0
	+1(0.5)	1	25	0	0
	+2(2.0)	0	0	20	0
	+3(6.0)	0	0	0	23
Total		932	25	20	23
Exact agreement %		99.90%	100%	100%	100%
Agreement ± 1 block %		100%	100%	100%	100%

Blood (N=1000) (ery/mcL)		URIT UC-1800 Automatic Urine Analyzer (11FA test strips)				
		-(0)	+-(10)	+1(25)	+2(80)	+3(200)
Predicate device (K082811) Uritest-500B urine analyzer (11G test strip)	-(0)	579	0	0	0	0
	+-(10)	0	160	1	0	0
	+1(25)	0	2	120	0	0
	+2(80)	0	0	0	55	0
	+3(200)	0	0	0	0	83
Total		579	162	121	55	83
Exact agreement %		100%	98.80%	99.20%	100%	100%
Agreement ± 1 block %		100%	100%	100%	100%	100%

Glucose (N=1000) (mg/dL)		URIT UC-1800 Automatic Urine Analyzer (11FA test strips)					
		-(0)	+-(50)	+1(100)	+2(250)	+3(500)	+3(1000)
Predicate device (K082811) Uritest-500B urine analyzer (11G test strip)	-(0)	810	0	0	0	0	0
	+-(50)	1	42	1	0	0	0
	+1(100)	0	0	26	0	0	0
	+2(250)	0	0	0	19	0	0
	+3(500)	0	0	0	0	30	1
	+3(1000)	0	0	0	0	0	70
Total		811	42	27	19	30	71
Exact agreement %		99.90%	100%	96.30%	100%	100%	98.60%
Agreement ± 1 block %		100%	100%	100%	100%	100%	100%

Protein (N=1000) (mg/dL)		URIT UC-1800 Automatic Urine Analyzer (11FA test strips)				
		-(0)	+-(15)	+1(30)	+2(100)	+3(300)
Predicate device (K082811) Uritest-500B urine analyzer (11G test strip)	-(0)	698	1	0	0	0
	+-(15)	0	95	1	0	0
	+1(30)	0	0	64	0	0
	+2(100)	0	0	1	60	1
	+3(300)	0	0	0	0	59
Total		698	96	66	60	60
Exact agreement %		100%	99.00%	97.00%	100%	98.30%
Agreement ± 1 block %		100%	100%	100%	100%	100%

PH (N=1000)		URIT UC-1800 Automatic Urine Analyzer (11FA test strips)								
		5.0	5.5	6.0	6.5	7.0	7.5	8.0	8.5	9.0
Predicate device (K082811) Uritest-500B urine analyzer (11G test strip)	5.0	161	2	0	0	0	0	0	0	0
	5.5	0	272	0	0	0	0	0	0	0
	6.0	0	1	212	0	0	0	0	0	0
	6.5	0	0	1	134	1	0	0	0	0
	7.0	0	0	0	3	111	0	0	0	0
	7.5	0	0	0	0	0	48	0	0	0
	8.0	0	0	0	0	0	0	27	0	0
	8.5	0	0	0	0	0	0	0	20	0
	9.0	0	0	0	0	0	0	0	0	7
Total		161	275	213	137	112	48	27	20	7
Exact agreement %		100%	98.90 %	99.50 %	97.80 %	99.10 %	100%	100%	100%	100%
Agreement ± 1 block %		100%	100%	100%	100%	100%	100%	100%	100%	100%

SG(N=1000)		URIT UC-1800 Automatic Urine Analyzer (11FA test strips)					
		1.005	1.010	1.015	1.020	1.025	1.030
Predicate device (K082811) Uritest-500B urine analyzer (11G test strip)	1.005	33	0	0	0	0	0
	1.010	0	134	3	0	0	0
	1.015	0	2	212	0	0	0
	1.020	0	0	0	273	0	0
	1.025	0	0	0	1	202	0
	1.030	0	0	0	0	2	138
Total		33	136	215	274	204	138
Exact agreement %		100%	98.50%	98.60%	99.60%	99.00%	100%
Agreement ± 1 block %		100%	100%	100%	100%	100%	100%

A method comparison study was conducted to compare the test system's performance on measuring microalbumin and creatinine with Mission® U120 Ultra Urine Analyzer (K142391) using 979 clinical urine samples, and the results are summarized in the tables below.

Microalbumin (N=979)		URIT UC-1800 Automatic Urine Analyzer (12FA test strips)			
		10mg/L	30mg/L	80mg/L	150mg/L
Predicate device (K142391) Mission® U120 Ultra Urine Analyzer Mission® Urinalysis Reagent Strips (Microalbumin/Creatinine)	10mg/L	527	8	0	0
	30mg/L	14	75	9	0
	80mg/L	0	7	168	3
	150mg/L	0	0	3	165
Total		541	90	180	168
Exact agreement %		97.41%	83.33%	93.33%	98.21%
Agreement ± 1 block %		100%	100%	100%	100%

Creatinine (N=979)		URIT UC-1800 Automatic Urine Analyzer (12FA test strips)				
		10mg/dL	50mg/dL	100mg/dL	200mg/dL	300mg/dL
Predicate device (K142391) Mission® U120 Ultra Urine Analyzer Mission® Urinalysis Reagent Strips (Microalbumin/Creatinine)	10mg/dL	52	3	0	0	0
	50mg/dL	3	303	5	0	0
	100mg/dL	0	4	418	7	0
	200mg/dL	0	0	7	151	2
	300mg/dL	0	0	0	4	20
Total		55	310	430	162	22
Complete agreement rate		94.55%	97.74%	97.21%	93.21%	90.91%
General agreement rate		100%	100%	100%	100%	100%

A method comparison study was conducted for color and turbidity, as measured on the analyzer, with the comparator AUTION MAX AX-4030 Urinalysis System (K093098). 1365 clinical urine samples were tested to cover all grades of color the test system detects, and 1000 clinical urine samples were tested for the analytical measurement range of turbidity. The comparison results of Color and Turbidity are summarized in the tables below.

Color		Comparator AX-4030							
		Colorless	Yellow	Red	Brown	Green	Orange	Blue	Violet
URIT UC-1800 Automatic Urine Analyzer	Colorless	283	10	0	0	0	0	0	0
	Yellow	27	717	1	0	0	4	0	0
	Red	0	2	63	1	0	0	0	2
	Brown	0	0	1	65	0	0	0	0
	Green	0	0	0	0	37	0	1	0
	Other	0	0	0	0	2	72	39	38
Total		310	729	65	66	39	76	40	40
Coincidence rate		91.29%	98.35%	96.92%	98.48%	94.87%	94.74%	97.50%	95.00%

Turbidity		Comparator AX-4030		
		-	+1	+2
UC1800	Clear	898	0	0
	Micro turbid	10	42	0
	Turbid	0	25	1
	Very turbid	0	0	24
Total		908	67	25
Coincidence rate		98.90%	100%	96.00%

2. Matrix Comparison:

Not applicable. This device is for testing with human urine only.

C Clinical Studies:

1. Clinical Sensitivity:

Not applicable.

2. Clinical Specificity:

Not applicable.

3. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):

Not applicable.

D Clinical Cut-Off:

Not applicable.

E Expected Values/Reference Range:

The Reference Range results were drawn from literatures and summarized in the table below.

Analyte	Reference Range	Analyte	Reference Range
Leukocytes	Negative	Specific Gravity	1.003～1.035
Ketone	Negative	pH	4.5～8.0
Nitrite	Negative	Blood	Negative
Urobilinogen	（0.2～1.0）EU/dL	Glucose	Negative
Bilirubin	Negative	Creatinine	(10～300) mg/dL
Protein	Negative	Microalbumin	＜20 mg/L
Ascorbic acid	2-10 mg/dL	/	/

F Other Supportive Instrument Performance Characteristics Data:

Not applicable.

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:

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