April 26, 2024

URIT Medical Electronic Co., Ltd.
c/o Dylan Wu, Consultant
Shanghai SUNGO Management Consutling Co., Ltd.
Room 1401, Dongfang Building, 1500# Century AVE
Shanghai 200122, China

Re: K232317
Trade/Device Name: UC-1800 Automatic Urine Analyzer, URIT 11FA Urine Reagent Strips, URIT 12FA Urine Reagent Strips
Regulation Number: 21 CFR 864.6550
Regulation Name: Occult Blood Test
Regulatory Class: Class II
Product Code: JIO, JIL, JFY, CDM, CEN, JIN, JJB, JMT, LJX, JRE, JMA, JIR, KQO
Dated: March 29, 2024
Received: March 29, 2024

Dear Dylan Wu:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Paula V. Caposino -S

Paula Caposino, Ph.D.
Deputy Division Director
Division of Chemistry and Toxicology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K232317

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

Indications for Use *(Describe)*
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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(K) Summary

K232317

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirement by 21 CFR 807.92

Date prepared: 25th, April 2024

1 Submitter's Information

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3 Subject Device

3.1 Trade Name and Regulatory Information:

No.	Trade name	Regulatory Information
1	UC-1800 Automatic Urine Analyzer	Class I §21 CFR 862.2900 Automated Urinalysis System
3	URIT 11FA Urine Reagent Strips	Class II (*Blood and Glucose analytes raise system to Class II / 510(k) required*)
4	URIT 12FA Urine Reagent Strips	Class II (*Blood, Glucose and Creatinine analytes raise system to Class II / 510(k) required*)

3.2 Classification Information

No.	Regulation 21 CFR Section	Product Code	Classification	Description	Panel
1	862.2900	KQO	Class I	Automated Urinalysis System	Clinical Chemistry
2	862.1225	JFY	Class II	Creatinine test System	Clinical Chemistry
3	862.1645	JIR	Class I	Protein or Albumin (Urinary, Non-Quant.)	Clinical Chemistry

No.	Regulation 21 CFR Section	Product Code	Classification	Description	Panel
4	862.1340	JIL	Class II	Glucose (Urinary, Non-Quantitative)	Clinical Chemistry
5	864.6550	JIO	Class II	Blood, Occult, Colorimetric, In Urine	Hematology
6	862.1785	CDM	Class I	Urobilinogen (Urinary Non-Quant.)	Clinical Chemistry
7	862.1550	CEN	Class I	pH (Urinary, Non-Quant.)	Clinical Chemistry
8	862.1435	JIN	Class I	Ketones (Urinary, Non-Quant.)	Clinical Chemistry
9	862.1645	JIR	Class I	Protein or Albumin (Urinary, Non-Quant.)	Clinical Chemistry
10	862.1115	JJB	Class I	Urinary Bilirubin & Its Conjugates (Urinary, Non-Quant.)	Clinical Chemistry
11	862.1510	JMT	Class I	Nitrite (Urinary, Non-Quant.)	Clinical Chemistry
12	864.7675	LJX	Class I	Leukocyte peroxidase test	Hematology
13	862.2800	JRE	Class I	Specific Gravity	Clinical Chemistry
14	862.1095	JMA	Class I	Ascorbic Acid Test System	Clinical Chemistry

4 Predicate device

510(k) Number: K082811
Uritest 500B Urine Analyzer
Uritest 50 Urine Analyzer
Uritest 10G Urine Reagent Strips
Uritest 11G Urine Reagent Strips

510(k) Number: K142391
Mission® U120 Ultra Urine Analyzer
Mission® Urinalysis Reagent Strips (Microalbumin/Creatinine)
Mission® Liquid Urine Controls, Mission® Liquid Diptube Urine Controls

510(k) Number: K093098
AUTION MAX AX-4030 Urinalysis System

5 Device Description

5.1 UC-1800 Automatic Urine Analyzer

UC-1800 Automatic Urine Analyzer is characterized by fully automated and simple operation. All you need to do is to set test strips and samples, press the START key, and the rest of operations are fully automated with UC-1800, which can measure samples continuously. For each measurement, the instrument automatically performs a series of operation: sample transmitting, sample aspirating, sample dropping, rinsing, strip sorting, strip feeding and color identifying, etc. The instrument is used in conjunction with a serial of URIT urine test strips for measuring 15 parameters. Measure results are printed through either built-in printer or external printer. The test principle of the device is described as below.

a Test strip measurement principle

Measurement of test strips is done by the reflectance photometry method.
Placing tube racks loaded with samples on the rack injection mechanism and clicking the START key, the instrument will automatically perform a series of operations, such as transmitting samples, selecting strips, reading barcode, aspirating

samples, dropping samples, measuring samples and printing results, until all tube racks are done. During the measurement, the reacted pads on strip (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 reflective light amount of each reacted pad with the reflective light amount of the calibration pad. The concentrations of analyzes 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 falls on the reacted pads and the calibration pad on the strip. The absorbent and reflective light amounts vary with the color of reagent pads. If the color is darker, more light is absorbed, and less light is reflected, vice versa. i.e., the degree of color development is proportional to the concentration of analyzes in urine. The reflectance is calculated using the following formula:

$$R\% = \frac{T_m \cdot C_s}{T_s \cdot C_m} \times 100\% \quad (1)$$

R: Reflectance

Tm: Reflective light amount at the reactive pad with the measurement wavelength

Ts: Reflective light amount at the reactive pad with the reference wavelength

Cm: Reflective light amount at the calibration pad with the measurement wavelength

Cs: Reflective light amount at the calibration pad with the reference wavelength

The reflected lights from reagent pads are transmitted in the optical unit and received by the light receptor, where the optical signals are transformed into electrical signals. Then the electrical signals are transformed through I/V converter, processed by CPU and finally printed out.

b Specific gravity measurement principle

Specific gravity measurement method is refractometer, which using the correlation between light refractive index and total solids in the solution to determine.

Refractometer method, available at 15℃~38℃ temperature range of use, before use can be calibrated by the temperature compensation device; available for use the known standard high specific gravity concentration solution and standard low specific gravity deionized water to calibrate; easy to standardization, less quantity of samples, especially suitable for patients with oliguria and pediatric patients. Refractometer method is recommended as reference method by Clinical Laboratory Standard Institution, CLSI and Chinese Committee for Clinical Laboratory Standards, CCCLS.

Specific gravity is based on the principle of different concentrations of urine sample which have different refractive indexes to measure, that is uses the same wavelength of monochromatic parallel light comes into the triple prism which contains urine sample, and then according to position of refracted ray in photoelectric technology detector（displacement sensor）to determine the specific gravity value. Specific gravity measurement principle functional block diagram is shown in Figure 1 below.

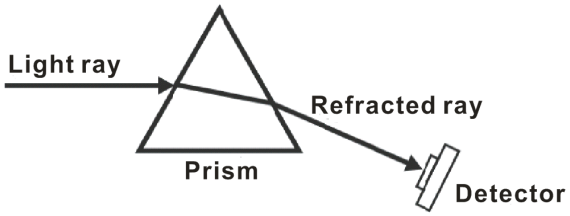

Figure 1 Specific gravity measurement principle

Specific gravity results are calculated by the following formulas:

$$SG_X = (SG_H - SG_L) \cdot \frac{K_X - K_L}{K_H - K_L} + SG_L \quad (2)$$

can change to

$$\frac{SG_X - SG_L}{SG_H - SG_L} = \frac{K_X - K_L}{K_H - K_L} \quad (3)$$

relationship between them is linear.

SG_H: The specific gravity of high concentration solution

SG_L: The specific gravity of low concentration solution

SG_X: The specific gravity of sample solution

K_H: High concentration solution position coefficient

K_L: Low concentration solution position coefficient

K_X: Sample solution position coefficient

Position coefficient: It is calculated by the detector output data, and has a linear relationship with the refractive index.

Refractive index change depends on the temperature of the sample solution, and the specific gravity value is using the following formula to correct.

$$SG_t = SG_X + (T_{SAM} - T_{STD}) \cdot C_t \quad (4)$$

SG_t: The specific gravity of high concentration solution

SG_X: The specific gravity of low concentration solution

T_{SAM}: The temperature of sample solution

T_{STD}: The temperature of low concentration solution

C_t: Temperature coefficient (SG 0.001/3°C) （temperature coefficient）

If the urine sample contains large amounts of glucose or protein, then the specific gravity will be affected, according to WS/T 229-229 "Physical, chemical and microscopic examination of urine" 5.4.1 requirements: 1 g/L protein will increase urine specific gravity 0.0003, 1 g/L glucose will increase urine specific gravity 0.0004. So, the specific gravity results will be corrected through the glucose and protein level which was measured by the test strip.

$$SG = SG_t - C_{GLU} - C_{PRO} \quad (5)$$

SG: Specific gravity value which after the temperature compensation

SG_t: Specific gravity value which gets from formula (4)

C_{GLU}: Glucose correction value

C_{PRO}: Protein correction value

c Turbidity measurement principle

Turbidity module emits light, to make it go through the sample, and then detect how much light is scattered by the particles in the water from the direction at a 90-degree angle to the incident light (The most stable angle of scattered light, is at a right angle to the center line of the incident light, so measuring the scattered light from 90 ° direction which can minimize the influence of particle size on scattering light intensity). This scattered light measurement method called scattering method. Turbidity measurement principle functional block diagram is shown in Figure 2 below.

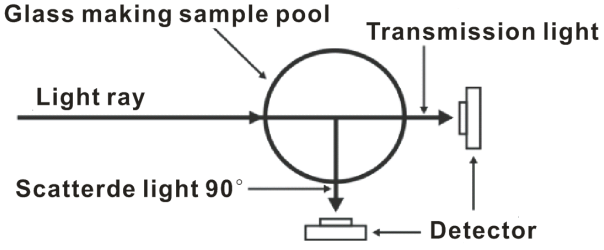

Figure 2 Turbidity measurement principle

Turbidity result is calculated by the following formula:

$$T = (S_S/T_S - S_W/T_W)/K \quad (6)$$

T: Turbidity level

S_S: Sample scattered light level

T_S: Sample transmission light level

S_W: Flushing fluid scattered light level

T_W: Flushing fluid transmission light level

K: Coefficient factor

d Color measurement principle

The color of often seen objects, are actually the objects surfaces absorb a part of chromatic light from the white light(sunlight) that fall on them, and then reflect the other part of chromatic light to human eyes' response. Various frequencies of visible light are mixed together become white, that is to say, it contains all sorts of color of light, such as red(R), yellow(Y), green(G), blue(B), purple(P). According to the German physicist Helinholtz's three primary colors theory, all sorts of color is made of different proportion of three primary colors (red, green, blue).

Primary colors are the "basic color" which cannot be gotten by other colors mixed. But mix the primary colors in different proportion will get other new colors. Three primary colors of light are RGB (Red, Green, and Blue). Equivalent red light +green light=yellow light, green light +blue light = cyan light. Equivalent red light +blue light = magenta light, equivalent red +green+ blue=white, and if the intensity of these three lights is zero, it is black (dark).

When the white light through colored solution, the non-solution colors light will be absorbed, so the color of the light through the solution can be expressed as the color of the solution, and then the solution color can be detected by the professional color recognition sensor (filter) which in the back-end of the solution.

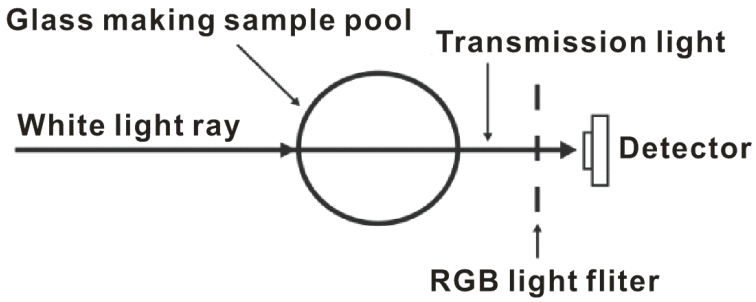

Figure 3 Principle of color detection

5.2 URIT 11FA/12FA urine reagent strips

Urine Reagent Strips is used to determine the components to be measured in urine by dry chemistry method together with urine analyzer. Various components to be tested in the 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. Qualitative and semi-quantitative detection can be conducted to the contents of the corresponding detected components. As a reagent for the determination of multiple components in human urine and the most basic test item for clinical urine analysis (urine routine test), it is suitable for the screening test or auxiliary diagnosis for clinical diagnosis, without the specificity for diseases or indications, and urine dry chemistry test is only used as a screening test and cannot be used as a single diagnostic method.

a Ascorbic Acid

Based on the principle of Tillman's Reagent, Ascorbic acid can reduce the dye from blue to red. The purpose of the determination of this project is to provide the user with the content of Ascorbic acid in the sample to determine its possible interference.

b 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.

c Microalbumin

Based on the dye-binding method, microalbumin can react with the dye to form a pink complex and generate produce a color change, which is particularly sensitive to the reaction of albumin.

d Leukocytes

Based on the principle of 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.

e 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.

f Ketone

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

g Urobilinogen

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

h Bilirubin

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

i Glucose

Based on the reaction principle of 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.

j Protein

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

k Blood

Based on the principle of hemoglobin contact activity method, the decomposition of peroxides can be catalyzed through the peroxidase-like action of hemoglobin, so that tetramethylbenzidine is oxidized and colored.

l Specific Gravity

Using the polyelectrolyte method, and 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.

m pH

The pH value within the range from 5.0 to 9.0 is measured by pH indicator, and the pH value of fresh urine of normal people is within the range from 5.5 to 7.0.

6 Indications for use/Intended 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.

7 Comparison of technological characteristics with the predicate device

Table 1 Technological characteristics of Proposed Device

Feature	UC-1800 Automatic Urine Analyzer
Methodology	Reflectance photometer
Principle	Measurement of test strips is done by the reflectance photometry method, using CIS (contact image sensor) image scanning analysis technology to detect.
Chemistry	URIT 11FA Urine Reagent Strips URIT 12FA Urine Reagent Strips
Throughput	480test/hour
Memory	2 million sample data and 100,000 sample pictures.
PC Port	PS/2 interface, serial port, Ethernet interface, USB interface
Capabilities	Barcode Scanner; Built-in thermal printer or external USB printer
Available Languages on Screen	Chinese or English
Environment requirement	15°C-30°C,RH ≤ 80%
Specimen ID enter	Manually enter or by bar code reader
Dimensions (L × W × H)	653mm×641mm×570mm
Power Source	AC 100V-240V~, 50/60Hz, three-core power supply, good grounding.
Weight	75kg
Calibration	The user can use the URIT urine control materials and calibration test strips to calibrate the instrument

7.1 Substantial Equivalence

The URIT 11FA/12FA Urine Reagent Strips and the URIT UC-1800 Automatic Urine Analyzer is substantially equivalent to the Uritest 11G Urine Reagent Strips and the Uritest-500B Urine Analyzer (K082811) except Microalbumin and Creatinine.

And the URIT 12FA Urine Reagent Strips and the URIT UC-1800 Automatic Urine Analyzer is substantially equivalent to the Mission® Urinalysis Reagent Strips (Microalbumin/Creatinine) and the Mission® U120 Ultra Urine Analyzer(K142391) Microalbumin and Creatinine only

And the URIT UC-1800 Automatic Urine Analyzer is substantially equivalent to AUTION MAX AX-4030 Urinalysis System (K093098) in detecting Specific Gravity, Turbidity and Color detected by Physical Module.

Table 2 Total review of proposed device and predicate devices

Device Name	Predicate Device Name	Predicate 510(K) number	Note
URIT UC-1800 Automatic Urine Analyzer	Uritest-500B Urine Analyzers	K082811	Except Microalbumin/Creatinine
	Mission® U120 Ultra Urine Analyzer	K142391	Microalbumin/Creatinine only
	AUTION MAX AX-4030 Urinalysis System	K093098	Specific Gravity, Turbidity and Color detected by Physical Module
URIT 11FA Urine Reagent Strips	Uritest 11G Urine Reagent Strips	K082811	N/A
URIT 12FA Urine Reagent Strips	Uritest 11G Urine Reagent Strips	K082811	Except Microalbumin/Creatinine
URIT 12FA Urine Reagent Strips	Mission® Urinalysis Reagent Strips (Microalbumin/Creatinine)	K142391	Microalbumin/Creatinine only

Table 3 Comparison with Predicate Devices (1)

Device	**Proposed Device (K232317)**	**Predicate Device 1(K082811)**	**Predicate Device 2(K142391)**	**Predicate Device 3（K093098）**
Manufacturer	URIT Medical Electronic Co., Ltd.	URIT Medical Electronic Co., Ltd.	Acon Laboratories, Inc.	ARKRAY, Inc.
Device name	**URIT UC-1800 Automatic Urine Analyzer**	**Uritest-500B Urine Analyzers**	**Mission® U120 Ultra Urine Analyzer**	**AUTION MAX AX-4030 Urinalysis System**
Similarities				
Classification	**Class II (*Blood, Glucose and Creatinine analytes raise system to Class II / 510(k) required*)**	**Class II (*Blood and Glucose analytes raise system to Class II / 510(k) required*)**	**Class II (*Creatinine analytes raise system to Class II / 510(k) required*)**	**Class II (*Blood and Glucose analytes raise system to Class II / 510(k) required*)**
Intended Use	**UC-1800 Automatic Urine Analyzer** is automated instruments which are 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 specific gravity, color and turbidity of urine. Test results may provide reference for clinical examination and diagnosis.	**Uritest-500B urine analyzer is** 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.	**The Mission U120 Ultra Urine Analyzer** is a urinalysis instrument intended for in vitro diagnostic use. It is intended for professional use only at point-of-care locations. The Mission U120 Ultra Urine Analyzer is intended to read Mission Urinalysis Reagent strips (Microalbumin/Creatinine) for the semi quantitative measurement of Albumin and Creatinine. These measurements are used to assist diagnosis for kidney function.	The AX-4030 is an automated urine analyzer that is designed to measure and analyze urine samples using measurements that include but are not limited to; Normal, STAT, Control and Check. These measurements are used to examine the following analytes; glucose (GLU), protein (PRO), bilirubin (BIL), urobilinogen (URO), pH (PH), blood (BLD), ketones (KET), nitrite (NIT) leukocytes (LEU) and specific gravity (S.G.). In addition, this device is used only with AUTION Sticks 9EB multi-parameter test strips.
Data Type	Qualitative, Semi-Quantitative	Qualitative, Semi-Quantitative	Semi-Quantitative	Semi-Quantitative
Location	**Clinical Laboratory**	**Clinical Laboratory**	**Clinical Laboratory**	**Clinical Laboratory**
Medical Device /IVD	**Medical Device /IVD**	**Medical Device /IVD**	**Medical Device /IVD**	**Medical Device /IVD**
Indications	For prescription use only.	For prescription use only.	For prescription use only.	For prescription use only.
Specimen Type	Human Urine	Human Urine	Human Urine	Human Urine
Analyte	With strips: Glucose, Blood, Urobilinogen, pH, Ketones, Protein, Bilirubin, Nitrite, Leukocyte, Specific Gravity, Ascorbic acid	Glucose, Blood, Urobilinogen, pH, Ketones, Protein, Bilirubin, Nitrite, Leukocyte, Specific Gravity, Ascorbic acid	N/A	N/A
	With strips: Creatinine, Microalbumin	N/A	Creatinine, Microalbumin	N/A
	With Physical module: Specific Gravity, Turbidity and Color	N/A	N/A	Specific Gravity, Turbidity and Color
Methodology/Principle	Test strips: Reflectance photometer, Measurement of test strips is done by the reflectance photometry method，using CIS (contact image sensor) image scanning analysis technology to detect. Specific Gravity: Refractometer method Color: Light-transmission measurement Turbidity: Light-scattering measurement method	Reflectance photometer (Only Test strips) Ingredients that change color in reaction with analytes	Reflectance photometer (Only Test strips) The Mission® U120 Ultra Urine Analyzer utilizes a CMOS image sensor to measure the intensity of light. The frequency of the light is determined by the LED light source.	(without Test Strips) Specific gravity: Reflection refractometry Color hue: Light-transmission measurement Turbidity: Light-scattering measurement method
Specimen ID enter	Manually enter or by bar code reader	Manually enter or by bar code reader	Manually enter or by bar code reader	Barcode Reader
Environment requirement	15°C-30°C,RH ≤ 80%	15°C-30°C,RH ≤ 80%	15-30ºC (59-86ºF); 20-80% Relative Humidity (noncondensing)	Temperature: 10-30°C,Humidity: 20-80% RH(No condensation)

Table 4 Comparison with Predicate Devices (2)

Device	Proposed Device (K232317)	Predicate Device 1(K082811)	Predicate Device 2(K142391)	Predicate Device 3(K142392)
Manufacturer	URIT Medical Electronic Co., Ltd.	URIT Medical Electronic Co., Ltd.	Acon Laboratories, Inc.	ARKRAY, Inc.
Device name	**URIT UC-1800 Automatic Urine Analyzer**	**Uritest-500B Urine Analyzers**	**Mission® U120 Ultra Urine Analyzer**	**AUTION MAX AX-4030 Urinalysis System**
Differences				
Chemistry	URIT 11FA Urine Reagent Strips URIT 12FA Urine Reagent Strips	Uritest 11G Urine Reagent Strips	Mission® Urinalysis Reagent Strips (Microalbumin/ Creatinine)	None
Available Languages on Screen	Chinese or English	Chinese or English	English and Spanish	English
Dimensions (L × W × H)	653mm×641mm×570mm	390 mm × 340 mm ×290 mm	26.0 (L) x 15.0 (W) x 17.5 (H) cm	530 (w) x 530(d) x 530 (h)(mm)
Power Source	AC 100V-240V~, 50/60Hz, three-core power supply, good grounding.	AC100-240V, 50/60Hz Input: 61VA	100- 240 VAC (adapter), (50-60Hz± 1HZ)6 AA batteries with 100 tests/6 new batteries;	100-240 VAC, 50/60 Hz
Weight	75kg	6.5 Kg	≤1.66 kg (3.65 lbs.) without batteries or power supply	41Kg (including the Sampler unit 4kg)
PC Port	PS/2 interface, serial port, Ethernet interface, USB interface	RS 232 port.	Standard RS232C Port (cable not included), USB Port (cable not included); (Not connect to PC) Bluetooth Wireless	RS-232C/ Ethernet
Capabilities	Barcode Scanner Built-in thermal printer or external USB printer	Internal or external Printer	Internal thermal printer Barcode reader Connector External printer (optional) Barcode reader (optional) RJ45 Ethernet; (optional)	Built-in printer
Calibration	The user can use the URIT urine control materials and calibration test strips to calibrate the instrument	Self-calibration---white calibration bar	The Mission® U120 Ultra Urine Analyzer performs an automatic calibration each time a test is run.	N/A
Throughput	480test/hour	500 tests/hour	Single Test Mode: 55 tests/hour. Continuous Test Mode: 120 tests/hour.	225 samples/hour
Memory	2 million sample data and 100,000 sample pictures.	1,000 results	Last 2000 test results	2500 tests

Characteristic of the URIT 11FA/12FA Urine Reagent Strips are compared with the Uritest 11G Urine Reagent Strips (K082811) for instrument reading in Table 5 to Table 7

Table 5 Comparison with Predicate Devices-Reagent strips (1)

Device	**Proposed Device**	**Predicate Device 1**
Manufacturer	URIT Medical Electronic Co., Ltd.	URIT Medical Electronic Co., Ltd.
510K number	**K232317**	K082811
Device name	**URIT 11FA Urine Reagent Strips** **URIT 12FA Urine Reagent Strips**	**Uritest 11G Urine Reagent Strips**
Classification	**Class II (*Blood, Glucose and Creatinine analytes raise system to Class II / 510(k) required*)**	**Class II (*Blood and Glucose analytes raise system to Class II / 510(k) required*)**
Intended Use	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. 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.	**Uritest 11G urine reagent strips** provide semi-quantitative tests for Ascorbic acid, Nitrite, Leukocyte, Ketone, Urobilinogen, Bilirubin, Glucose, Protein, Blood, Specific Gravity, PH in urine. The Uritest 11 G 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 **The strips are read instrumentally by the Uritest-500B Urine Analyzers**
Indications	Professional in vitro diagnostic use	Same
Analytes	URIT 11FA/12FA Urine Reagent Strips: Nitrite, Leukocyte, Ketone, Urobilinogen, Bilirubin, Glucose, Protein, Blood, Specific Gravity, PH URIT 11FA Urine Reagent Strips also provide the detection of Ascorbic acid, While URIT 12FA Urine Reagent Strips provide the detection of microalbumin and creatinine (Predicated with K142391)	Ascorbic acid, Nitrite, Leukocyte, Ketone, Urobilinogen, Bilirubin, Glucose, Protein, Blood, Specific Gravity, PH
Specimen	Human Urine	Same
Architecture	Firm plastic, dry reagent strips	Same
Storage	Store at 2°C-30°C	Same

Table 6 Comparison with Predicate Devices-Reagent strips (2)

Device	**Proposed Device**	**Predicate Device 1**
Manufacturer	URIT Medical Electronic Co., Ltd.	URIT Medical Electronic Co., Ltd.
510K number	**K232317**	K082811
Device name	**URIT 11FA Urine Reagent Strips** **URIT 12FA Urine Reagent Strips**	**Uritest 11G Urine Reagent Strips**
Classification	**Class II (*Blood, Glucose and Creatinine analytes raise system to Class II / 510(k) required*)**	**Class II (*Blood and Glucose analytes raise system to Class II / 510(k) required*)**
Test Principle	Ingredients that change color in reaction with analytes	Same
Blank block (calibrator)	The distribution of urine on the test block and the color of the urine itself will generally cause errors to the measurement results. The purpose of setting the blank block is to eliminate these factors that may cause error, and the same blank block is used for each project.	Same
Ascorbic acid	Based on the principle of Tillman's Reagent, Ascorbic acid can reduce the dye from blue to red. The purpose of the determination of this project is to provide the user with the content of Ascorbic acid in the sample to determine its possible interference.	Same
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 naphthylethylenediamine dihydrochloride to show a pink color.	Same
Microalbumin	Based on the dye-binding method, microalbumin can react with the dye to form a pink complex and generate produce a color change, which is particularly sensitive to the reaction of albumin.	None
Leukocyte	Based on the principle of 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.	Same
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	None
Ketone	Based on the principle of sodium nitro prussiate method, sodium nitroprusside can interact with ketone (acetoacetate) under alkaline conditions to become purple, especially acetoacetate is particularly sensitive to this.	Same
Urobilinogen	Based on the principle of azo-binding method, urobilinogen is coupled with diazonium salt under strong acid conditions to form carmine pigment.	Same
Bilirubin	Based on the principle of azo-coupling method,2,4-dichloroaniline diazonium salt can react specifically with bilirubin, and produce different colors depending on the concentration of bilirubin.	Same
Glucose	Based on the reaction principle of 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.	Same
Protein	Based on the principle of protein error method of dye binding, the protein can combine with the dye to form a complex that produce a color change, especially the response to albumin is more sensitive than that of globulin, hemoglobin, Bence-Jone protein and mucin.	Same
Blood	Based on the principle of hemoglobin contact activity method, the decomposition of peroxides can be catalyzed through the peroxidase-like action of hemoglobin, so that tetramethylbenzidine is oxidized and colored.	Same
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.	Same
PH	The pH value within the range from 5.0 to 9.0 is measured by pH indicator, and the pH value of fresh urine of normal people is within the range from 5.5 to 7.0.	Same
Detection Range	Ascorbic Acid (10-100) mg/dL	Same
	Nitrite (+/-)	Same
	Leukocytes (15-500)leu/mcL	Same
	Ketone (5-80) mg/dL	Same
	Urobilinogen (2-8)EU/dL	Same
	Bilirubin (0.5-6.0) mg/dL	Same
	Glucose (50-1000) mg/dL	Same
	Protein(15-300)mg/dL	Same
	Blood (10-200) ery/mcL	Same
	Specific Gravity 1.005-1.030	Same
	pH 5.0-9.0	Same

Characteristic of the URIT 12FA Urine Reagent Strips in detecting Microalbumin and creatinine are compared with the Mission® Urinalysis Reagent Strips (Microalbumin/Creatinine) (K142391) read by Mission® U120 Ultra Urine Analyzer in Table 7.

Table 7 Comparison with Predicate Devices-Reagent strips (3)

Device	**Proposed Device**	**Predicate Device 2**
Manufacturer	URIT Medical Electronic Co., Ltd.	Acon Laboratories, Inc.
510K number	**K232317**	K142391
Device name	**URIT 12FA Urine Reagent Strips (Only Microalbumin/Creatinine)**	**Mission® Urinalysis Reagent Strips (Microalbumin/Creatinine)**
Classification	**Class II**	**Class II**
Similarities		
Intended Use	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.	The Mission Urinalysis Reagent strips (Microalbumin/Creatinine) are intended for the semi quantitative measurement of albumin and creatinine in urine samples using the Mission U120 Ultra Urine Analyzer. These measurements are used to assist diagnosis for kidney function. It is intended for professional use only at point-of-care locations. **The strips are read instrumentally by the Mission® U120 Ultra Urine Analyzer**
Indications	Professional in vitro diagnostic use	Professional use in point-of-care urine testing
Analytes	Microalbumin and Creatinine	Microalbumin and creatinine
Specimen	Human Urine	Human Urine
Architecture	Firm plastic, dry reagent strips	Plastic strips affixed with two separate reagent areas.
Differences		
Test Principle	Ingredients that change color in reaction with analytes	Intensity of the light reflected from the reagent areas of a urinalysis reagent strip.
Storage	Store at 2°C-30°C	Store at 15°C-30°C
Microalbumin Detection Methodology	Based on the dye-binding method, microalbumin can react with the dye to form a pink complex and generate produce a color change, which is particularly sensitive to the reaction of albumin.	This test is based on dye binding using a high affinity sulfone phthalein dye. At a constant pH, the development of any blue color is due to the presence of albumin. The resulting color ranges from pale green to aqua blue
Creatinine Detection Methodology	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.	This test is based on the peroxidase-like activity of a copper creatinine complex that catalyzes the reaction of diisopropylbenzene dihydroperoxide and 3,3',5,5'- tetramethylbenzidine. The resulting color ranges from orange through green to blue
Detection Range	Microalbumin (10-150) mg/L	Detects albumin between 10-150mg/L
	Creatinine(10-300)mg/dL	Detects creatinine between 10-300 mg/dL (0.9 - 26.5 mmol/L)

Therefore, it can be concluded that the subject device and the proposed device are substantially equivalent.

8 Summary of Non-Clinical Testing

8.1 Analytical performance

a Precision /Reproducibility

The Repeatability (With-in Run) Precision of the URIT UC-1800 Automatic Urine Analyzer was evaluated by using negative urines and spiked urines of known concentrations for each analyte. Each sample was tested in 20 replicates across 3 instruments with the 3lots of URIT 11FA Urine Reagent Strips and 3lots of URIT 12FA Urine Reagent Strips in each instrument for a total of 60 measurements at each concentration. All concentrations for all tests had 60 of 60 (100%) match at ± one color block. The results are summarized in Table 8 to Table 11.

Table 8 Summary of Repeatability (With-in Run) Precision of URIT 11FA Urine Reagent Strips

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)	
Conclusion	Qualified	Qualified	Qualified	Qualified	Qualified	
Nitrite	- (Negative)	+ (Positive)				
Exact agreement	100% (60/60)	100% (60/60)				
± 1 color block	100% (60/60)	100% (60/60)				
Conclusion	Qualified	Qualified				
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)	
± 1 color block	100% (60/60)	100% (60/60)	100% (60/60)	100% (60/60)	100% (60/60)	
Conclusion	Qualified	Qualified	Qualified	Qualified	Qualified	
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)	
Conclusion	Qualified	Qualified	Qualified	Qualified	Qualified	
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)	
Conclusion	Qualified		Qualified	Qualified	Qualified	
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)	
Conclusion	Qualified		Qualified	Qualified	Qualified	
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)
Conclusion	Qualified	Qualified	Qualified	Qualified	Qualified	Qualified
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)	
Conclusion	Qualified	Qualified	Qualified	Qualified	Qualified	
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)
Conclusion	Qualified	Qualified	Qualified	Qualified	Qualified	Qualified

Test	Expected Value					
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)	
Conclusion	Qualified	Qualified	Qualified	Qualified	Qualified	
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)
Conclusion	Qualified	Qualified	Qualified	Qualified	Qualified	Qualified
pH	8.0	8.5	9.0			
Exact agreement	100% (60/60)	100% (60/60)	100% (60/60)			
± 1 color block	100% (60/60)	100% (60/60)	100% (60/60)			
Conclusion	Qualified	Qualified	Qualified			

Table 9 Summary of Repeatability (With-in Run) Precision of URIT 12FA Urine Reagent Strips

Test	Expected Value					
Nitrite	- (Negative)	+ (Positive)				
Exact agreement	100% (60/60)	100% (60/60)				
± 1 color block	100% (60/60)	100% (60/60)				
Conclusion	Qualified	Qualified				
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)	
± 1 color block	100% (60/60)	100% (60/60)	100% (60/60)	100% (60/60)	100% (60/60)	
Conclusion	Qualified	Qualified	Qualified	Qualified	Qualified	
Ketone (mg/dL)	-(0)	+-(5)	+1(15)	+2(40)	+3(80)	
Exact agreement	100% (60/60)	100% (60/60)	96.7% (58/60)	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)	
Conclusion	Qualified	Qualified	Qualified	Qualified	Qualified	
Urobilinogen (EU/dL)	Normal		+1(2.0)	+2(4.0)	+3(8.0)	
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)	
Conclusion	Qualified		Qualified	Qualified	Qualified	
Bilirubin (mg/dL)	-(0)		+1(0.5)	+2(2.0)	+3(6.0)	
Exact agreement	100% (60/60)		98.3% (59/60)	91.7% (55/60)	100% (60/60)	
± 1 color block	100% (60/60)		100% (60/60)	100% (60/60)	100% (60/60)	
Conclusion	Qualified		Qualified	Qualified	Qualified	
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)
Conclusion	Qualified	Qualified	Qualified	Qualified	Qualified	Qualified
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)	
Conclusion	Qualified	Qualified	Qualified	Qualified	Qualified	
Specific Gravity	1.005	1.010	1.015	1.020	1.025	1.030
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)

Test	Expected Value					
Conclusion	Qualified	Qualified	Qualified	Qualified	Qualified	Qualified
Blood(CELL/μL)	-(0)	+-(10)	+1(25)	+2(80)	+3(200)	
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)	
Conclusion	Qualified	Qualified	Qualified	Qualified	Qualified	
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)	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)
Conclusion	Qualified	Qualified	Qualified	Qualified	Qualified	Qualified
pH	8.0	8.5	9.0			
Exact agreement	100% (60/60)	100% (60/60)	100% (60/60)			
± 1 color block	100% (60/60)	100% (60/60)	100% (60/60)			
Conclusion	Qualified	Qualified	Qualified			
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)		
Conclusion	Qualified	Qualified	Qualified	Qualified		
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)	
Conclusion	Qualified	Qualified	Qualified	Qualified	Qualified	

Table 10 Summary of Repeatability (With-in Run) Precision of Physical Module Item Turbidity

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)
Conclusion	Qualified	Qualified	Qualified	Qualified

Table 11 Summary of Repeatability (With-in Run) Precision of Physical Module Item Color

Test	Color	Exact agreement	Conclusion
Expected Value	Colorless	100% (60/60)	Qualified
	Brown	100% (60/60)	Qualified
	Yellow	100% (60/60)	Qualified
	Red	100% (60/60)	Qualified
	Green	100% (60/60)	Qualified
	Other-Orange	100% (60/60)	Qualified
	Other-Blue	100% (60/60)	Qualified
	Other-Purple	100% (60/60)	Qualified

The Reproducibility (Between-Run) Precision of the URIT UC-1800 Automatic Urine Analyzer was evaluated by using negative urines and spiked urines of known concentrations for each analyte. Each sample was tested for 20days with 2 runs per day, in 1 time per run in 3 sites, each site with 1 instrument, totally the test performed across 3 instruments with the 3lots of URIT 11FA Urine Reagent Strips and 3lots of URIT 12FA Urine Reagent Strips in each instrument by 3 operators, each operator performing the test for 6-7 days, for a total of 120 measurements at each concentration were tested. All

concentrations for all tests had 120 of 120 (100%) match at ± one color block. The results are summarized in Table 12 to Table 15.

Table 12 Summary of Reproducibility (Between-Run) Precision of URIT 11FA Urine Reagent Strips

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)	
Conclusion	Qualified	Qualified	Qualified	Qualified	Qualified	
Nitrite	- (Negative)	+ (Positive)				
Exact agreement	100% (120/120)	100% (120/120)				
± 1 color block	100% (120/120)	100% (120/120)				
Conclusion	Qualified	Qualified				
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)	
Conclusion	Qualified	Qualified	Qualified	Qualified	Qualified	
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)	
Conclusion	Qualified	Qualified	Qualified	Qualified	Qualified	
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)	
Conclusion	Qualified		Qualified	Qualified	Qualified	
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)	
Conclusion	Qualified		Qualified	Qualified	Qualified	
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)
Conclusion	Qualified	Qualified	Qualified	Qualified	Qualified	Qualified
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)	
Conclusion	Qualified	Qualified	Qualified	Qualified	Qualified	
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)
Conclusion	Qualified	Qualified	Qualified	Qualified	Qualified	Qualified
Blood(CELL/μL)	-(0)	+-(10)	+1(25)	+2(80)	+3(200)	
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)	
Conclusion	Qualified	Qualified	Qualified	Qualified	Qualified	
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)

Test	Expected Value					
± 1 color block	100% (120/120)	100% (120/120)	100% (120/120)	100% (120/120)	100% (120/120)	100% (120/120)
Conclusion	Qualified	Qualified	Qualified	Qualified	Qualified	Qualified
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)			
Conclusion	Qualified	Qualified	Qualified			

Table 13 Summary of Reproducibility (Between-Run) Precision of URIT 12FA Urine Reagent Strips

Test	Expected Value					
Nitrite	- (Negative)	+ (Positive)				
Exact agreement	100% (120/120)	100% (120/120)				
± 1 color block	100% (120/120)	100% (120/120)				
Conclusion	Qualified	Qualified				
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)	
Conclusion	Qualified	Qualified	Qualified	Qualified	Qualified	
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)	
Conclusion	Qualified	Qualified	Qualified	Qualified	Qualified	
Urobilinogen (EU/dL)	Normal		+1(2.0)	+2(4.0)	+3(8.0)	
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)	
Conclusion	Qualified		Qualified	Qualified	Qualified	
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)	
Conclusion	Qualified		Qualified	Qualified	Qualified	
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)
Conclusion	Qualified	Qualified	Qualified	Qualified	Qualified	Qualified
Protein(mg/dL)	-(0)	+-(15)	+1(30)	+2(100)	+3(300)	
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)	
Conclusion	Qualified	Qualified	Qualified	Qualified	Qualified	
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)
Conclusion	Qualified	Qualified	Qualified	Qualified	Qualified	Qualified
Blood(CELL/μL)	-(0)	+-(10)	+1(25)	+2(80)	+3(200)	
Exact agreement	100% (120/120)	100% (120/120)	100% (120/120)	95.8% (115/120)	99.2% (119/120)	
± 1 color block	100% (120/120)	100% (120/120)	100% (120/120)	100% (120/120)	100% (120/120)	
Conclusion	Qualified	Qualified	Qualified	Qualified	Qualified	

Test	Expected Value					
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)	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)
Conclusion	Qualified	Qualified	Qualified	Qualified	Qualified	Qualified
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)			
Conclusion	Qualified	Qualified	Qualified			
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)		
Conclusion	Qualified	Qualified	Qualified	Qualified		
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)	
Conclusion	Qualified	Qualified	Qualified	Qualified	Qualified	

Table 14 Summary of Reproducibility (Between- Run) Precision of Physical Module Item Turbidity

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)
Conclusion	Qualified	Qualified	Qualified	Qualified

Table 15 Summary of Reproducibility (Between- Run) Precision of Physical Module Item Color

Test	Color	Exact agreement	Conclusion
Expected Value	Colorless	100% (120/120)	Qualified
	Brown	100% (120/120)	Qualified
	Yellow	100% (120/120)	Qualified
	Red	100% (120/120)	Qualified
	Green	100% (120/120)	Qualified
	Other-Orange	100% (120/120)	Qualified
	Other-Blue	100% (120/120)	Qualified
	Other-Purple	100% (120/120)	Qualified

b Linearity/assay reportable range

The assay reportable range was evaluated by measuring the samples containing known concentrations of all measurement blocks. Prepare the reference solutions according to the marked values of concentration for each item on the URIT 11FA and 12FA urine reagent strips, and conduct linear range/reportable range experiments on the instrument with the reference solutions. Test each reference solution on three UC-1800 machines with three batches of reagent strips. Repeat the test for each batch of test strip for 21 times on each instrument.

The results of assay reportable range of URIT 11FA Urine Reagent Strips and URIT 12FA Urine Reagent Strips are summarized as Table 16 to Table 18 show below. The Summary of Reportable Results of URIT 11FA Urine Reagent Strips and URIT 12FA Urine Reagent Strips are summarized as Table 19 show below.

Table 16 Summary of Linearity of URIT 11/12FA Urine Reagent Strips -common analytes

Analyte	URIT 11/12 FA Urine Reagent Strips (Common Item)				
	Qualitative Rank	Semi-Quantitative Rank	Concentration/Level Tested	Agreement at same block	Agreement within +/- one block
Leukocyte	-	0	0 leu/mcL	100% (63/63)	100% (63/63)
	+/-	15	15 leu/mcL	100% (63/63)	100% (63/63)
	+1	70	70 leu/mcL	100% (63/63)	100% (63/63)
	+2	125	125 leu/mcL	100% (63/63)	100% (63/63)
	+3	500	500 leu/mcL	100% (63/63)	100% (63/63)
Ketones	-	0	0 mg/dL	100% (63/63)	100% (63/63)
	+/-	5	5 mg/dL	100% (63/63)	100% (63/63)
	+1	15	15 mg/dL	100% (63/63)	100% (63/63)
	+2	40	40 mg/dL	100% (63/63)	100% (63/63)
	+3	80	80 mg/dL	100% (63/63)	100% (63/63)
Urobilinogen	Normal	Normal	Normal	100% (63/63)	100% (63/63)
	+1	2.0	2.0 mg/dL	100% (63/63)	100% (63/63)
	+2	4.0	4.0 mg/dL	100% (63/63)	100% (63/63)
	+3	8.0	8.0 mg/dL	100% (63/63)	100% (63/63)
Bilirubin	-	0	0 mg/dL	100% (63/63)	100% (63/63)
	+1	0.5	0.5 mg/dL	100% (63/63)	100% (63/63)
	+2	2.0	2.0 mg/dL	100% (63/63)	100% (63/63)
	+3	6.0	6.0 mg/dL	100% (63/63)	100% (63/63)
Glucose	-	0	0 mg/dL	100% (63/63)	100% (63/63)
	+/-	50	50 mg/dL	100% (63/63)	100% (63/63)
	+1	100	100 mg/dL	100% (63/63)	100% (63/63)
	+2	250	250 mg/dL	100% (63/63)	100% (63/63)
	+3	500	500 mg/dL	100% (63/63)	100% (63/63)
	+4	1000	1000 mg/dL	100% (63/63)	100% (63/63)
Protein	-	0	0 mg/dL	100% (63/63)	100% (63/63)
	+/-	15	15 mg/dL	100% (63/63)	100% (63/63)
	+1	30	30 mg/dL	100% (63/63)	100% (63/63)
	+2	100	100 mg/dL	100% (63/63)	100% (63/63)
	+3	300	300 mg/dL	100% (63/63)	100% (63/63)
Blood	-	0	0 ery/mcL	100% (63/63)	100% (63/63)
	+/-	10	10 ery/mcL	100% (63/63)	100% (63/63)
	+1	25	25 ery/mcL	100% (63/63)	100% (63/63)
	+2	80	80 ery/mcL	100% (63/63)	100% (63/63)
	+3	200	200 ery/mcL	100% (63/63)	100% (63/63)
Specific Gravity	N/A	1.005	1.005	100% (63/63)	100% (63/63)
		1.010	1.010	100% (63/63)	100% (63/63)
		1.015	1.015	100% (63/63)	100% (63/63)
		1.020	1.020	100% (63/63)	100% (63/63)
		1.025	1.025	100% (63/63)	100% (63/63)
		1.030	1.030	100% (63/63)	100% (63/63)
pH	N/A	5.0	5.0	100% (63/63)	100% (63/63)
		5.5	5.5	100% (63/63)	100% (63/63)

Analyte	URIT 11/12 FA Urine Reagent Strips (Common Item)				
	Qualitative Rank	Semi-Quantitative Rank	Concentration/Level Tested	Agreement at same block	Agreement within +/- one block
		6.0	6.0	100% (63/63)	100% (63/63)
		6.5	6.5	100% (63/63)	100% (63/63)
		7.0	7.0	100% (63/63)	100% (63/63)
		7.5	7.5	100% (63/63)	100% (63/63)
		8.0	8.0	100% (63/63)	100% (63/63)
		8.5	8.5	100% (63/63)	100% (63/63)
		9.0	9.0	100% (63/63)	100% (63/63)

Table 17 Summary of Linearity of URIT 11FA Urine Reagent Strips

Analyte	URIT 11 FA Urine Reagent Strips				
	Qualitative Rank	Semi-Quantitative Rank	Concentration/Level Tested	Agreement at same block	Agreement within +/- one block
Ascorbic acid	-	0	0mg/dL	100% (63/63)	100% (63/63)
	+1	10	10mg/dL	100% (63/63)	100% (63/63)
	+2	25	25mg/dL	100% (63/63)	100% (63/63)
	+3	50	50mg/dL	100% (63/63)	100% (63/63)
	+4	100	100mg/dL	100% (63/63)	100% (63/63)

Table 18 Summary of Report range of URIT 12FA Urine Reagent Strips

Analyte	URIT 12FA Urine Reagent Strips (Microalbumin & Creatinine)			
	Semi-Quantitative Rank	Concentration/Level Tested	Agreement at same block	Agreement within +/- one block
Microalbumin	10	10mg/L	100% (63/63)	100% (63/63)
	30	30mg/L	100% (63/63)	100% (63/63)
	80	80mg/L	100% (63/63)	100% (63/63)
	150	150mg/L	100% (63/63)	100% (63/63)
Creatinine	10	10mg/dL	100% (63/63)	100% (63/63)
	50	50mg/dL	100% (63/63)	100% (63/63)
	100	100mg/dL	100% (63/63)	100% (63/63)
	200	200mg/dL	100% (63/63)	100% (63/63)
	300	300mg/dL	100% (63/63)	100% (63/63)

Table 19 Summary of Reportable Results of URIT 11/12FA Urine Reagent Strips

Item	URIT Urine Reagent Strips	
	11FA	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
Leukocyte	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	

Item	URIT Urine Reagent Strips	
	11FA	12FA
Bilirubin	0,0.5,2.0,6.0mg/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	

c Analytical Sensitivity

The results of Analytical Sensitivity of URIT 11FA Urine Reagent Strips and URIT 12FA Urine Reagent Strips are summarized as Table 20.

Table 20 Summary of Analytical Sensitivity of Urine Reagent Strips

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

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

The results of Critical value of URIT 11FA Urine Reagent Strips and URIT 12FA Urine Reagent Strips are summarized as Table 21 show.

Table 21 Summary of Critical value of Urine Reagent Strips

Analyte	Concentration	Critical value	Agreement rate%	
			11FA	12FA
Ascorbic acid	25 (1+)	12 mg/dL	76	N/A
	50 (2+)	32 mg/dL	89	
	100 (3+)	72 mg/dL	66	
Microalbumin	8	5.2mg/dL	N/A	88
	15	11.3mg/dL		79
Leukocyte	70(1+)	38 leu/mcL	92	74
	125(2+)	88 leu/mcL	85	64
	500 (3+)	337 leu/mcL	77	69
Creatinine	100	74mg/dL	N/A	77
	200	142mg/dL		75
	300	239mg/dL		79

Analyte	Concentration	Critical value	Agreement rate%	
			11FA	12FA
Ketone	15 (1+)	8 mg/dL	82	74
	40 (2+)	25 mg/dL	82	76
	80(3+)	63 mg/dL	72	71
Urobilinogen	4 (2+)	1.8 EU/dL	81	77
	8 (3+)	4.5 EU/dL	71	74
Bilirubin	2(2+)	1.3 mg/dL	88	78
	6(3+)	3 mg/dL	79	73
Glucose	100 (1+)	75 mg/dL	86	73
	250 (2+)	165 mg/dL	77	74
	500（3+）	360 mg/dL	66	76
	1000 (4+)	735 mg/dL	71	74
Protein	30 (1+)	21 mg/dL	77	83
	100 (2+)	65 mg/dL	75	70
	300 (3+)	180 mg/dL	79	70
Blood	25 (1+)	16 ery/mcL	79	77
	80 (2+)	65 ery/mcL	77	79
	200 (3+)	130 ery/mcL	79	71
pH	5.5	5.2	83	73
	6	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

d Analytical specificity

d.1 Exogenous and Endogenous Interference

Select urine sample and mix it well to prepare negative samples for each dry chemistry item. Prepare the first positive-grade sample (excluding pH and specific gravity) by adding the substance to be tested, Dissolve the interfering substance with an appropriate solvent according to the chemical properties of the interfering substance. The concentration of the stock solution shall be appropriate to reduce dilution of the basic sample matrix. The dilution ratio of the sample matrix shall not exceed 5%, Absorb an appropriate volume of interfering substance stock solution according to a certain proportion and add it into the volumetric flask, and then fix to the scale with the basic sample to prepare a sample containing a single interfering substance. The concentration of interfering substances in different samples is shown in Table 22.

Table 22 Interfering substance and concentration

Interfering substance	Concentration	Interfering substance	Concentration	Interfering substance	Concentration
Exogenous interfering substances				**Endogenous interfering substances**	
Acetaminophen	300 mg/dL	Quaternary Ammonium	200mg/dL	Hydroxybutyrate dehydrogenase	450 mg/dL
Amoxicillin	1333 mg/dL	Lithium acetoacetate	250 mg/dL	Ammonium chloride	2500 mg/dL
Ascorbic acid	400 mg/dL	Peroxide	10%	Bilirubin	170 mg/dL
Biotin	100 mg/dL	Peroxidase	20mg/dL	Calcium chloride	300 mg/dL
Cefoxitin	1200 mg/dL	Sodium thiosulfate	20mg/dL	Creatinine	1500 mg/dL
Furosemide	200 mg/dL	Potassium chloride	1500 mg/dL	Glucose	10000mg/dL
Gabapentin	1200 mg/dL	Sodium Bicarbonate	1500 mg/dL	HGB	83 mg/dL
Gentamicin sulphate	40 mg/dL	Citric acid	150 mg/dL	Protein	500 mg/dL
Ibuprofen	250 mg/dL	Creatine	10mg/dl	Nitrite	11 mg/dL
Levodopa	125 mg/dL	Fructose	100mg/dL	Urea	20000 mg/dL
Lisinopril	27 mg/dL	Galactose	80 mg/dL	Urea acid	155mg/dL
Metformin	850 mg/dL	Oxalic acid	70mg/dl	Urobilinogen	300mg/dL
Methyldopa	200 mg/dL	Vitamin B	10mg/dl	Human immunoglobulin IgG	500mg/dL
Methylamine + methylene blue	400 + 66.5mg/dL	Sodium acetate	2.25mg/dl	Leukocyte	2500leu/uL
Acetylcysteine	20 mg/dL	Sodium chloride	5500mg/dl	Cysteine	20mg/dL
Ofloxacin	90 mg/dL	Sodium nitrate	10mg/dl	Blood	0.05%
Phenazopyridine	30 mg/dL	Sodium phosphate	500mg/dl	Glycine	450 mg/dL
Salicylic acid	600 mg/dL	Theophylline	100 mg/dL	Lactose	10mg/dl
Tetracycline	50 mg/dL			Leukocyte	2500leu/uL

Add the solvent of the same volume as the experimental sample (the solvent used to prepare the stock solution) into the second volumetric flask and fix to the scale with the basic sample. Each sample (experimental sample and control sample) shall be tested for five times on two UC-1800 machines, two batch numbers of 11FA and 12FA reagent strips. Results are summarized in the tables below.

1. The substances show no interference for all analytes

The following substances, i.e. Cefoxitin, Ofloxacin, Phenazopyridine, Salicylic acid, Tetracycline, Hydroxybutyrate dehydrogenase, Protein, Lactose, Leukocyte, Potassium chloride, Citric acid, Creatine, Fructose, Galactose, Oxalic acid, Vitamin B, Sodium acetate, Sodium chloride, Sodium nitrate, Theophylline show no interference for all analytes at tested concentration. The Results are summarized in Table 23.

Table 23 The substances that do not cause interference

Interfering substance	Maximum concentration without interference
Cefoxitin	1200 mg/dL
Ofloxacin	90 mg/dL

Interfering substance	Maximum concentration without interference
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
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

2.The substances that cause interference

For those substances that on initial screening where found to interfere with certain analytes, dose response testing was conducted to establish the concentration limit below which no significant interference is expected. The results are given in the tables below

Table 24 The substances that cause interference

Analyte	Interfering substances	Maximum concentration without interference（mg/dL）	Interference concentration (mg/dL)	Specific interference effect	Strip
Leukocyte	Urobilinogen	25	50	From - to +- (False Positive)	URIT 11/12 FA Urine Reagent Strips
			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)	
			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)	URIT 11/12 FA Urine Reagent Strips
	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)	
	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)	URIT 11/12 FA Urine Reagent Strips
	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)	URIT 11/12 FA Urine Reagent Strips
			50	From - to 2 (False Positive)	
			25	From 1 to 2 (elevated positive result)	
	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)	URIT 11/12 FA Urine Reagent Strips
	Peroxide	5%	7.50%	From - to +- (False Positive)	
			7.50%	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	10050	15025	From +- to - (False Negative)	
Protein	Quaternary Ammonium	50	100	From - to +- (False Positive)	URIT 11/12 FA Urine Reagent Strips
			150	From - to 1 (False Positive)	
			100	From +- to 1 (elevated positive result)	
			150	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 positive result)	
	Ibuprofen	62.5	125	From +- to - (False Negative)	
	Methylamine + methylene blue	66.7+11.7	200+35	From - to +- (False Positive)	
			100+17.5	From +- to 1+ (elevated positive result)	
	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	1500	From - to +-/1+ (False Positive and elevated positive result)	
			750	From +- to 1+ (elevated positive result)	
	HGB	1250	3750	From - to +-/1+ (False Positive and elevated positive result)	
			2500	From +- to 1+ (elevated positive result)	
	Urea	10050	15025	From +- to 1+ (elevated positive result)	

Analyte	Interfering substances	Maximum concentration without interference（mg/dL）	Interference concentration (mg/dL)	Specific interference effect	Strip
Blood	Peroxidase	5	10	From - to +- (False Positive)	URIT 11/12 FA Urine Reagent Strips
			10	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)	
	Methylamine + methylene blue	66.7+11.7	100+17.5	From - to +- (False Positive)	
			100+17.5	From +- to 1+ (elevated positive result)	
Specific Gravity	Salicylic acid	300	450	From 1.010 to 1.020 (Result rise)	URIT 11/12 FA Urine Reagent Strips
			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)	URIT 11/12 FA Urine Reagent Strips
	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)	URIT 11 FA Urine Reagent Strips
			15	From +- to 1 (elevated positive result)	
	Cysteine	10	15	From - to +- (False Positive)	
			15	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 10mg/L to 30mg/L (False Positive)	URIT 12 FA Urine Reagent Strips
			100	From 30mg/L to 80mg/L (elevated positive result)	
	Blood	0.0375%	0.05%	From 10mg/L to 30mg/L (False Positive)	
			0.05%	From 30mg/L to 80mg/L (elevated positive result)	
	Human immunoglobulin lgG	41.67	83.33	From 10mg/L to 30mg/L (False Positive)	
			375	From 10mg/L to 80mg/L (False Positive)	
			83.33	From 30mg/L to 80mg/L (elevated positive result)	
			375	From 30mg/L to 150mg/L (elevated positive result)	
	Ascorbic acid	200	300	From 30 mg/L to 10 mg/L (False Negative)	
	Gabapentin	7.5	30	From 10 mg/L to 30 mg/L (False Positive)	
			15	From 30 mg/L to 80 mg/L (elevated positive result)	
	Methylamine + methylene blue	66.7+11.7	100 + 17.5	From 10mg/L to 30mg/L (False Positive)	
			200+35	From 30mg/L to 80mg/L (elevated positive result)	
	Ammonium chloride	625	1250	From30mg/L to 10mg/L (False Negative)	
	Creatinine	600	1500	From10mg/L to 30mg/L (False Positive)	
			750	From30mg/L to 80mg/L (elevated positive result)	
	HGB	83	830	From10mg/L to 30mg/L (False Positive)	
			208	From30mg/L to 80mg/L (elevated positive result)	
Creatinine	Acetaminophen	225	300	From 50 mg/dL to 100 mg/dL (elevated positive result	URIT 12 FA Urine Reagent Strips
	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	200	From 10 mg/dL to 50 mg/dL (False Positive)	
			5	From 50 mg/dL to 100 mg/dL (elevated positive result)	
	Ammonium chloride	100	104.2	From 50 mg/dL to 10 mg/dL (False Negative)	

d.2 Effect of urine pH

Collect mixed negative urine samples and divide them into 5 parts. Adjust their pH values with 1M hydrochloric acid aqueous solution and 1M sodium hydroxide aqueous solution to prepare samples with pH value of 4.5, 5.5, 6.5, 7.5, and 8.5, respectively. Each sample shall be tested for 5 times on 2 UC-1800 machines, two batch numbers of 11FA and 12FA test strips, respectively. For all test strip analytes, except leukocytes and specific gravity, For leukocytes, urine pH values lower than 5.5 may yield a false negative result. For specific gravity , No significant interference was observed for the urine pH ranges from 5.5 to 7.5 , Urine pH values lower than 5.5 may yield a false increased of Specific Gravity, and urine pH values higher than 7.5 may yield decreased of specific gravity. The results were summarized as Table 25 shows.

Table 25 Summary of effect of urine pH

Item	**URIT 11/12 FA Urine Reagent Strips**	
	No interference pH	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)

d.3 Effect of urine color

Collect mixed negative urine samples and divide them into 3 parts. Use bovine hemoglobin, sunset yellow, lignin, Lemon yellow, Naphthol green, Bright blue and Crystal violet to prepare the samples into the red, orange, brown, yellow, green, blue, purple samples. Each sample shall be tested for 5 times on two UC-1800 machines, two batch numbers of 11FA and 12FA test strips, respectively. All the results demonstrated that all color showed no interference on each analyte. The results were summarized as Table 26 to Table 31 shows.

Table 26 Summary of effect of urine color – Red, Orange, Brown (11/12FA)

Analyte	Concentration	URIT 11/12FA Urine Reagent Strips					
		Red		Orange		Brown	
		HGB Concentration	Result	Sunset yellow Concentration	Result	Lignin Concentration	Result
Leukocyte	- (0 leu/mcL)	0,750,300 mg/L	No interference	0,312.5,150 mg/L	No interference	0;1;0.4 mg/L	No interference
	+/- (15 leu/mcL)	0,750,300 mg/L	No interference	0,312.5,150 mg/L	No interference	0;1;0.4 mg/L	No interference
Ketones	- (0 mg/dL)	0,750,300 mg/L	No interference	0,312.5,150 mg/L	No interference	0;1;0.4 mg/L	No interference
	+/- (5 mg/dL)	0,750,300 mg/L	No interference	0,312.5,150 mg/L	No interference	0;1;0.4 mg/L	No interference
Urobilinogen	Normal (Normal)	0,750,300 mg/L	No interference	0,312.5,150 mg/L	No interference	0;1;0.4 mg/L	No interference
	1 (2.0 mg/dL)	0,750,300 mg/L	No interference	0,312.5,150 mg/L	No interference	0;1;0.4 mg/L	No interference
Bilirubin	- (0 mg/dL)	0,750,300 mg/L	No interference	0,312.5,150 mg/L	No interference	0;1;0.4 mg/L	No interference
	1 (0.5 mg/dL)	0,750,300 mg/L	No interference	0,312.5,150 mg/L	No interference	0;1;0.4 mg/L	No interference
Glucose	- (0 mg/dL)	0,750,300 mg/L	No interference	0,312.5,150 mg/L	No interference	0;1;0.4 mg/L	No interference
	+/- (50 mg/dL)	0,750,300 mg/L	No interference	0,312.5,150 mg/L	No interference	0;1;0.4 mg/L	No interference
Protein	- (0 mg/dL)	0,750,300 mg/L	No interference	0,312.5,150 mg/L	No interference	0;1;0.4 mg/L	No interference
	+/- (15 mg/dL)	0,750,300 mg/L	No interference	0,312.5,150 mg/L	No interference	0;1;0.4 mg/L	No interference
Blood	- (0 ery/mcL)	0,750,300 mg/L	No interference	0,312.5,150 mg/L	No interference	0;1;0.4 mg/L	No interference
	+/- (10 ery/mcL)	0,750,300 mg/L	No interference	0,312.5,150 mg/L	No interference	0;1;0.4 mg/L	No interference
Specific Gravity	1.015 (1.015)	0,750,300 mg/L	No interference	0,312.5,150 mg/L	No interference	0;1;0.4 mg/L	No interference
	1.020 (1.020)	0,750,300 mg/L	No interference	0,312.5,150 mg/L	No interference	0;1;0.4 mg/L	No interference
pH	6.5 (6.5)	0,750,300 mg/L	No interference	0,312.5,150 mg/L	No interference	0;1;0.4 mg/L	No interference
	7.5 (7.5)	0,750,300 mg/L	No interference	0,312.5,150 mg/L	No interference	0;1;0.4 mg/L	No interference
Nitrite	- (0 mg/dL)	0,750,300 mg/L	No interference	0,312.5,150 mg/L	No interference	0;1;0.4 mg/L	No interference
	+ (0.5 mg/dL)	0,750,300 mg/L	No interference	0,312.5,150 mg/L	No interference	0;1;0.4 mg/L	No interference

Table 27 Summary of effect of urine color – Yellow, Green, Blue, Purple (11/12FA)

Analyte	Concentration	URIT 11/12FA Urine Reagent Strips							
		Yellow		Green		Blue		Purple	
		Lemon yellow Concentration	Result	Naphthol green Concentration	Result	Bright blue Concentration	Result	Crystal violet Concentration	Result
Leukocyte	- (0 leu/mcL)	0;20;3 mg/L	No interference	0;40;20 mg/L	No interference	0;10;1 mg/L	No interference	0;10;3 mg/L	No interference
	+/- (15 leu/mcL)	0;20;3 mg/L	No interference	0;40;20 mg/L	No interference	0;10;1 mg/L	No interference	0;10;3 mg/L	No interference
Ketones	- (0 mg/dL)	0;20;3 mg/L	No interference	0;40;20 mg/L	No interference	0;10;1 mg/L	No interference	0;10;3 mg/L	No interference
	+/- (5 mg/dL)	0;20;3 mg/L	No interference	0;40;20 mg/L	No interference	0;10;1 mg/L	No interference	0;10;3 mg/L	No interference
Urobilinogen	Normal (Normal)	0;20;3 mg/L	No interference	0;40;20 mg/L	No interference	0;10;1 mg/L	No interference	0;10;3 mg/L	No interference
	1 (2.0 mg/dL)	0;20;3 mg/L	No interference	0;40;20 mg/L	No interference	0;10;1 mg/L	No interference	0;10;3 mg/L	No interference
Bilirubin	- (0 mg/dL)	0;20;3 mg/L	No interference	0;40;20 mg/L	No interference	0;10;1 mg/L	No interference	0;10;3 mg/L	No interference
	1 (0.5 mg/dL)	0;20;3 mg/L	No interference	0;40;20 mg/L	No interference	0;10;1 mg/L	No interference	0;10;3 mg/L	No interference
Glucose	- (0 mg/dL)	0;20;3 mg/L	No interference	0;40;20 mg/L	No interference	0;10;1 mg/L	No interference	0;10;3 mg/L	No interference
	+/- (50 mg/dL)	0;20;3 mg/L	No interference	0;40;20 mg/L	No interference	0;10;1 mg/L	No interference	0;10;3 mg/L	No interference
Protein	- (0 mg/dL)	0;20;3 mg/L	No interference	0;40;20 mg/L	No interference	0;10;1 mg/L	No interference	0;10;3 mg/L	No interference
	+/- (15 mg/dL)	0;20;3 mg/L	No interference	0;40;20 mg/L	No interference	0;10;1 mg/L	No interference	0;10;3 mg/L	No interference
Blood	- (0 ery/mcL)	0;20;3 mg/L	No interference	0;40;20 mg/L	No interference	0;10;1 mg/L	No interference	0;10;3 mg/L	No interference
	+/- (10 ery/mcL)	0;20;3 mg/L	No interference	0;40;20 mg/L	No interference	0;10;1 mg/L	No interference	0;10;3 mg/L	No interference
Specific Gravity	1.015 (1.015)	0;20;3 mg/L	No interference	0;40;20 mg/L	No interference	0;10;1 mg/L	No interference	0;10;3 mg/L	No interference
	1.02 (1.02)	0;20;3 mg/L	No interference	0;40;20 mg/L	No interference	0;10;1 mg/L	No interference	0;10;3 mg/L	No interference
pH	6.5 (6.5)	0;20;3 mg/L	No interference	0;40;20 mg/L	No interference	0;10;1 mg/L	No interference	0;10;3 mg/L	No interference
	7.5 (7.5)	0;20;3 mg/L	No interference	0;40;20 mg/L	No interference	0;10;1 mg/L	No interference	0;10;3 mg/L	No interference
Nitrite	- (0 mg/dL)	0;20;3 mg/L	No interference	0;40;20 mg/L	No interference	0;10;1 mg/L	No interference	0;10;3 mg/L	No interference
	+ (0.5 mg/dL)	0;20;3 mg/L	No interference	0;40;20 mg/L	No interference	0;10;1 mg/L	No interference	0;10;3 mg/L	No interference

Table 28 Summary of effect of urine color - Red, Orange, Brown (11FA)

Analyte	Concentration	Red		Orange		Brown	
		HGB Concentration	Result	Sunset yellow Concentration	Result	Lignin Concentration	Result
Ascorbic acid	- (0 mg/dL)	0,750,300 mg/L	No interference	0,312.5,150 mg/L	No interference	0;1;0.4 mg/L	No interference
	+/- (10 mg/dL)	0,750,300 mg/L	No interference	0,312.5,150 mg/L	No interference	0;1;0.4 mg/L	No interference

Table 29 Summary of effect of urine color – Yellow, Green, Blue, Purple (11FA)

Analyte	Concentration	Yellow		Green		Blue		Purple	
		Lemon yellow Concentration	Result	Naphthol green Concentration	Result	Bright blue Concentration	Result	Crystal violet Concentration	Result
Ascorbic acid	- (0 mg/dL)	0;20;3 mg/L	No interference	0;40;20 mg/L	No interference	0;10;1 mg/L	No interference	0;10;3 mg/L	No interference
	+/- (10 mg/dL)	0;20;3 mg/L	No interference	0;40;20 mg/L	No interference	0;10;1 mg/L	No interference	0;10;3 mg/L	No interference

Table 30 Summary of effect of urine color - Red, Orange, Brown (12FA)

Analyte	Concentration	Red		Orange		Brown	
		HGB Concentration	Result	Sunset yellow Concentration	Result	Lignin Concentration	Result
Microalbumin	0 mg/L	0,750,300 mg/L	No interference	0,312.5,150 mg/L	No interference	0;1;0.4 mg/L	No interference
	30 mg/L	0,750,300 mg/L	No interference	0,312.5,150 mg/L	No interference	0;1;0.4 mg/L	No interference
Creatinine	0 mg/dL	0,750,300 mg/L	No interference	0,312.5,150 mg/L	No interference	0;1;0.4 mg/L	No interference
	50 mg/dL	0,750,300 mg/L	No interference	0,312.5,150 mg/L	No interference	0;1;0.4 mg/L	No interference

Table 31 Summary of effect of urine color – Yellow, Green, Blue, Purple (12FA)

Analyte	Concentration	Yellow		Green		Blue		Purple	
		Lemon yellow Concentration	Result	Naphthol green Concentration	Result	Bright blue Concentration	Result	Crystal violet Concentration	Result
Microalbumin	0 mg/L	0;20;3 mg/L	No interference	0;40;20 mg/L	No interference	0;10;1 mg/L	No interference	0;10;3 mg/L	No interference
	30 mg/L	0;20;3 mg/L	No interference	0;40;20 mg/L	No interference	0;10;1 mg/L	No interference	0;10;3 mg/L	No interference
Creatinine	0 mg/dL	0;20;3 mg/L	No interference	0;40;20 mg/L	No interference	0;10;1 mg/L	No interference	0;10;3 mg/L	No interference
	50 mg/dL	0;20;3 mg/L	No interference	0;40;20 mg/L	No interference	0;10;1 mg/L	No interference	0;10;3 mg/L	No interference

d.1 Effect of urine Specific Gravity

Collect mixed negative urine samples and divide them into 10 parts. Use sodium chloride to adjust their specific gravity to prepare the samples with specific gravity of 1.005, 1.010, 1.015, 1.020, 1.025, 1.030, 1.035, 1.040, 1.045, and 1.050 respectively. Each sample shall be tested for 5 times on two UC-1800 machines, two batch numbers of 11FA and 12FA test strips.

Table 32 Summary of Effect of urine Specific Gravity

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

e Assay Cut-off

The results of assay Cut-off of URIT 11FA Urine Reagent Strips and URIT 12FA Urine Reagent Strips are summarized as Table 33.

Table 33 Summary of Analytical Sensitivity of Urine Reagent Strips

Analyte	Concentration	URIT 11FA Urine Reagent Strips		URIT 12FA Urine Reagent Strips	
		Cut-off	Agreement%	Cut-off	Agreement%
Glucose mg/dL	100 (1+)	75	86	75	73
	250 (2+)	165	77	165	74
	500 (3+)	360	66	360	76
	1000 (4+)	735	71	735	74
Blood ery/mcL	25 (1+)	16	79	16	77
	80 (2+)	65	77	65	79
	200 (3+)	130	79	130	71
Urobilinogen EU/dL	4 (2+)	1.8	81	1.8	77
	8 (3+)	4.5	71	4.5	74
Ketones mg/dL	15 (2+)	8	82	8	74
	40(3+)	25	82	25	76
	80(4+)	63	72	63	71
Protein mg/dL	30（1+）	21	77	21	83
	100 (2+)	65	75	65	70
	300 (3+)	180	79	180	70
Bilirubin mg/dL	2(2+)	1.3	88	1.3	78
	6(3+)	3	79	3	73
Leukocyte leu/mcL	70(1+)	38	92	38	74
	125(2+)	88	85	88	64
	500 (3+)	337	77	337	69
pH	5.5	5.2	83	5.2	73
	6.0	5.8	86	5.8	79
	6.5	6.3	82	6.3	77
	7.0	6.7	81	6.7	78
	7.5	7.3	76	7.3	82
	8.0	7.8	82	7.8	76
	8.5	8.2	72	8.2	94
	9.0	8.8	68	8.8	77
Ascorbic acid mg/dL	25 (1+)	12	76	N/A	N/A
	50 (2+)	32	89	N/A	N/A
	100 (3+)	72	66	N/A	N/A
Creatinine (mg/dL)	100	N/A	N/A	6.5	77
	200	N/A	N/A	12.5	75
	300	N/A	N/A	21	79
Microalbumin mg/L	80	N/A	N/A	52	88
	150	N/A	N/A	113	79

f Carryover

Evaluate the carryover by alternately testing the high-concentration samples (UQ14 NO. II/III) and low-concentration samples (UQ14 NO. I), namely, conduct tests in the sequence of high, low, high, low, high, low, high, low, high and low. For all

analytes, all negative/normal samples are read to be negative/normal. UC-1800 automatic urine analyzer with 11FA, 12FA test strip test carryover verification meets the requirements (All low-value samples are negative.). The results of carryover presented in Table 34 below.

Table 34 Summary of Carryover of Urine Reagent Strips

Test strip type	URIT 11FA Urine Reagent Strips	URIT 12FA Urine Reagent Strips
Nitrite	Qualified	Qualified
Leukocytes	Qualified	Qualified
Ketone	Qualified	Qualified
Urobilinogen	Qualified	Qualified
Bilirubin	Qualified	Qualified
Glucose	Qualified	Qualified
Protein	Qualified	Qualified
Blood	Qualified	Qualified
Ascorbic acid	Qualified	N/A
Microalbumin	N/A	Qualified
Creatinine	N/A	Qualified

g Reference Range

The Reference Range Result were confirmed as Table 35 shows below and listed in the IFU of Urine Reagent Strips.

Table 35 Reference Range Result of Urine Reagent Strips

Item	Reference value (reference interval)	Item	Reference value (reference interval)
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	/	/

The Reference Ranges are included in the labeling and are taken from literature references:

1. Shchersten B, Fritz H. Subnormal Levels of Glucose in Urine. JAMA 201:129-132, 1967.

2. McGarry JD, Lilly. Lecture, 1978: New Perspectives in the Regulation of Ketogenesis. Diabetes 28: 517-523 May, 1978.

3. Williamson DH. Physiological Ketoses, or Why Ketone Bodies? Postgrad. Med. J. (June Suppl.): 372-375, 1971.

4. Paterson P, et al. Maternal and Fetal Ketone Concentrations in Plasma and Urine. Lancet: 862-865; April 22, 1967.

5. Fraser J, et al. Studies with a Simplified Nitroprusside Test for Ketone Bodies in Urine, Serum, Plasma and Milk. Clin. Chem. Acta II: 372-378, 1965.

6. Henry JB, et al. Clinical Diagnosis and Management by Laboratory Methods, 20th Ed. Philadelphia. Saunders. 371-372, 375, 379, 382, 385, 2001.

7. Tietz NW. Clinical Guide to Laboratory Tests. W.B. Saunders Company. 1976.

8. Position Statement: Diabetic Nephropathy. Diabetes Care 20: S24-S27; 1997.

9. Burtis, C.A. and Ashwood, E.R.: Tietz Textbook of Clinical Chemistry, 3rd ed. Philadelphia: Saunders; 1999; pp. 483-484.

10. Mangili, R. et al.: Prevalence of Hypertension and Microalbuminuria in Adult Type 1 (Insulin Dependent) Diabetic Patients without Penal Failure in Italy – Validation of Screening techniques to detect microalbuminuria, Acta Diabetol. 29: 156-166; 1992.

11. American Diabetes Association, Clinical Practice Recommendations, Diabetes Care, Vol. 31, Suppl. 1, January 2008.

h Traceability

Each assay of the UC-1800 Automatic urinalysis test System is traceable to the following standards.

No	Analyte	Reference Method	Standardization
1	Ascorbic Acid	2,6-Dichlorophenolindophenol Titration Method	Ascorbic Acid
2	Nitrite	Diazotization colorimetric method	Sodium nitrite
3	Leukocytes	WBC counting method	Leukocyte esterase
4	Ketone	Lange method	Lithium acetoacetate
5	Urobilinogen	Ehrlich acetaldehyde test tube reaction method	2,5-dimethylpyrrole
6	Bilirubin	Biochemical testing/Dichloroaniline Diazo Salt Method	Bilirubin standard Bilirubin substitute TB
7	Glucose	glucose oxidase method	Glucose purity standard substance, glucosum anhydricum
8	Protein	Human serum albumin standard substance, Bovine serum albumin	Human serum albumin standard substance, Bovine serum albumin
9	Blood	Erythrometry	Bovine hemoglobin albumin
10	Specific Gravity	Specific gravity measurement	Specific gravity standard buffer
11	pH	Acidometer measurement	pH buffer solution (pH 4.0，6.86，9.18)
12	Microalbumin	Biochemical test Biochemical immunoturbidimetry	Human serum albumin
13	Creatinine	Biochemical test Biochemical immunoturbidimetry	Creatinine standard
14	Turbidity	Direct turbidimeter measurement method	Turbidity standard buffer
15	Color	Direct method of measurement of Sysmex UC3500	Pigments

8.2 Comparison Studies

a Method comparison with predicate device

a.1 Comparison with Automatic Urine Analyzer URIT-500B(K082811)

A total of 1000 clinical urine samples were collected for the experiment of comparison with Automatic Urine Analyzer URIT-500B(K082811), and the comparison results presented in the tables below.

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
Complete agreement rate		100%	100%	99.00%	97.60%	98.00%
General agreement rate		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
Complete agreement rate		99.40%	98.10%	98.20%	95.80%	100%
General agreement rate		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
Complete agreement rate		99.90%	100%	97.40%	97.40%	98.00%
General agreement rate		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
Complete agreement rate		99.90%	97.70%	96.70%	100%
General agreement rate		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
Complete agreement rate		99.90%	100%	100%	100%
General agreement rate		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
Complete agreement rate		100%	98.80%	99.20%	100%	100%
General agreement rate		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
Complete agreement rate		99.90%	100%	96.30%	100%	100%	98.60%
General agreement rate		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
Complete agreement rate		100%	99.00%	97.00%	100%	98.30%
General agreement rate		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
Complete agreement rate		100%	98.90%	99.50%	97.80%	99.10%	100%	100%	100%	100%
General agreement rate		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
Complete agreement rate		100%	98.50%	98.60%	99.60%	99.00%	100%
General agreement rate		100%	100%	100%	100%	100%	100%

Leukocyte (N=1000) (Leu/mcL)		URIT UC-1800 Automatic Urine Analyzer (12FA 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	106	3	0
	+2(125)	0	0	1	69	0
	+3(500)	0	0	0	0	76
Total		535	209	108	72	76
Complete agreement rate		99.40%	98.10%	98.10%	95.80%	100%
General agreement rate		100%	100%	100%	100%	100%

Ketone(N=1000) (mg/dL)		URIT UC-1800 Automatic Urine Analyzer (12FA 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
Complete agreement rate		99.90%	100%	97.40%	97.40%	98.00%
General agreement rate		100%	100%	100%	100%	100%

Nitrite (N=1000)		URIT UC-1800 Automatic Urine Analyzer (12FA 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 (12FA 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	1	28	0
	+3(8.0)	0	0	0	26
Total		901	44	29	26
Complete agreement rate		99.90%	95.50%	96.60%	100%
General agreement rate		100%	100%	100%	100%

Bilirubin(N=1000) (mg/dL)		URIT UC-1800 Automatic Urine Analyzer (12FA 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	24	1	0
	+2(2.0)	0	0	20	0
	+3(6.0)	0	0	0	23
Total		932	24	21	23
Complete agreement rate		99.90%	100%	95.20%	100%
General agreement rate		100%	100%	100%	100%

Blood (N=1000) (ery/mcL)		URIT UC-1800 Automatic Urine Analyzer (12FA 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
Complete agreement rate		100%	98.80%	99.20%	100%	100%
General agreement rate		100%	100%	100%	100%	100%

Glucose (N=1000) (mg/dL)		URIT UC-1800 Automatic Urine Analyzer (12FA 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	1	69
Total		811	42	27	19	31	70
Complete agreement rate		99.90%	100%	96.30%	100%	96.80%	98.60%
General agreement rate		100%	100%	100%	100%	100%	100%

Protein (N=1000) (mg/dL)		URIT UC-1800 Automatic Urine Analyzer (12FA 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	94	2	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	95	67	60	60
Complete agreement rate		100%	98.90%	95.50%	100%	98.30%
General agreement rate		100%	100%	100%	100%	100%

PH(N=1000)		URIT UC-1800 Automatic Urine Analyzer (12FA 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	2	211	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	276	212	137	112	48	27	20	7
Complete agreement rate		100%	98.60%	99.50%	97.80%	99.10%	100%	100%	100%	100%
General agreement rate		100%	100%	100%	100%	100%	100%	100%	100%	100%

SG(N=1000)		URIT UC-1800 Automatic Urine Analyzer (12FA 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	3	211	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	137	214	274	204	138
Complete agreement rate		100%	97.80%	98.60%	99.60%	99.00%	100%
General agreement rate		100%	100%	100%	100%	100%	100%

a.2 *Comparison with Mission® U120 Ultra Urine Analyzer (K142391)*

A total of 979 clinical urine samples were collected for the experiment of comparison with Mission® U120 Ultra Urine

Analyzer (K142391), and the Comparison results presented 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
Complete agreement rate		97.41%	83.33%	93.33%	98.21%
General agreement rate		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.3 *Comparison with AUTION MAX AX-4030 Urinalysis System (K093098)*

a.3.1 Color

Collect 1365 clinical urine samples, and the sample results shall cover all grades of color of predicate device AX-4030. The test shall be completed within 2h, and the time interval of test between different instruments shall be controlled within 2h. According to the requirements of product instructions, conduct comparison test on the ARKRAY AUTION MAX AX-4030 and UC 1800 automatic urine analyzer (physical module mode), once for each sample (retest if the results are abnormal due to instrument failure), and record the color results. After completing the test, review and compare the results; before test, quality control calibration shall be carried out on the corresponding instruments to ensure accuracy of the instruments. The comparison results of Color are presented in the Table 36 below.

Table 36 The comparison results of two methods-Color

Color		AX-4030							
		Colorless	Yellow	Red	Brown	Green	Orange	Blue	Violet
UC1800	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%
Conclusion		Qualified	Qualified	Qualified	Qualified	Qualified	Qualified	Qualified	Qualified

a.3.2 Turbidity

Collect 1000 clinical urine samples, and the sample results shall cover all grades of turbidity of predicate device AX-4030. The test shall be completed within 2h, and the time interval of test between different instruments shall be controlled within 2h. According to the requirements of product instructions, conduct comparison test on the ARKRAY AUTION MAX AX-4030 and UC 1800 automatic urine analyzer (physical module mode), once for each sample (retest if the results are abnormal due to instrument failure), and record the Turbidity results. After completing the test, review and compare the results; before test, quality control calibration shall be carried out on the corresponding instruments to ensure accuracy of the instruments.
The comparison results of Turbidity are presented in the Table 37 below.

Table 37 The comparison results of two methods- Turbidity

Turbidity		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%

b Matrix comparison

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

9 Clinical Test Conclusion

No clinical study is included in this submission.

9.1 <u>Clinical studies</u>

a Clinical Sensitivity

Not applicable

b Clinical specificity

Not applicable

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

Not applicable

10 Stability Test Conclusion

10.1 <u>URIT 11FA Urine Reagent Strips</u>

After a study on the stability of Urine Reagent Strips in the shelf life, the results show: various performance indexes of the Urine Reagent Strips within 25 months after being stored at 30℃ (extreme storage condition) all meet the relevant performance index requirements in the technical requirements for the product, which meets the requirement that the validity period of the Urine Reagent Strips is expected to be 24 months. Therefore, in consideration of design margin, we determine that the shelf life of Urine Reagent Strips is 24 months.

After a study on Open bottle stability, the results show: various performance indexes of the Urine Reagent Strips stored at 30℃(extreme storage condition),humidity ≤ 80% for 14 weeks after opening all meet the performance index requirements in the technical requirements for the product, but various performance indexes at the 15th week do not meet these requirements. To be prudent, we determine that the validity period of Urine Reagent Strips after opening is 3 months (12 weeks) after opening at 30℃(extreme storage condition),humidity ≤ 80%. The Urine Reagent Strips within the shelf life and the validity period after opening has reliable properties and can bring accurate and reliable test results as reference for clinical diagnosis.

After a study on stability during simulant transport, after the Urine Reagent Strips are stored respectively at the high

temperature of 50°C, at the low temperature of -20°C, and at the high temperature of 40°C and a high humidity of no less than 80% for 30 days, they are stored at 2°C to 30°C in a dry and dark place until the validity period expires, and compared with Urine Reagent Strips always stored on the conditions specified in the instructions, their performance indexes remain basically unchanged and meet the appearance and performance index requirements in the technical requirements for the product, which shows that the performance of the product is accurate and reliable during transport (within 30 days) even under extremely harsh transport conditions.

In addition, various performance indexes of the Urine Reagent Strips within 25 hours after being put in the reagent strip bin of Automatic Urine Analyzer on experimental conditions all meet the relevant performance index requirements in the technical requirements for the product. To be prudent, we determine that the On-board stability time of Urine Reagent Strips is 24 hours.

10.2 URIT 12FA Urine Reagent Strips

After a study on the stability of Urine Reagent Strips in the shelf life, the results show: various performance indexes of the Urine Reagent Strips within 25 months after being stored at 30°C (extreme storage condition) all meet the relevant performance index requirements in the technical requirements for the product, which meets the requirement that the validity period of the Urine Reagent Strips is expected to be 24 months. Therefore, in consideration of design margin, we determine that the shelf life of Urine Reagent Strips is 24 months.

After a study on Open bottle stability, the results show: various performance indexes of the Urine Reagent Strips stored at 30°C (extreme storage condition),humidity ≤ 80% for 14 weeks after opening all meet the performance index requirements in the technical requirements for the product, but various performance indexes at the 15th week do not meet these requirements. To be prudent, we determine that the validity period of Urine Reagent Strips after opening is 3 months (12 weeks) after opening at 30°C(extreme storage condition),humidity ≤ 80%. The Urine Reagent Strips within the shelf life and the validity period after opening

has reliable properties and can bring accurate and reliable test results as reference for clinical diagnosis.

After a study on stability during simulant transport, after the Urine Reagent Strips are stored respectively at the high temperature of 50°C, at the low temperature of -20°C, and at the high temperature of 40°C and a high humidity of no less than 80% for 30 days, they are stored at 2°C to 30°C in a dry and dark place until the validity period expires, and compared with Urine Reagent Strips always stored on the conditions specified in the instructions, their performance indexes remain basically unchanged and meet the appearance and performance index requirements in the technical requirements for the product, which shows that the performance of the product is accurate and reliable during transport (within 30 days) even under extremely harsh transport conditions.

In addition, various performance indexes of the Urine Reagent Strips within 25 hours after being put in the reagent strip bin of Automatic Urine Analyzer on experimental conditions all meet the relevant performance index requirements in the technical requirements for the product. To be prudent, we determine that the On-board stability time of Urine Reagent Strips is 24 hours.

11 Conclusion

The analytical performance studies and stability studies demonstrated substantial equivalency between the proposed device and predicate devices. Which demonstrated that the URIT 11FA Urine Reagent Strips and URIT 12FA Urine Reagent Strips read by URIT UC-1800 Automatic Urine Analyzer are safe, effective and such are substantially equivalent to the Uritest 11G Urine Reagent Strips read by the Uritest-500B Urine Analyzer (K082811) currently sold on the U.S. market for professional use in detecting Ascorbic acid, Nitrite, Leukocyte, Creatinine, Ketone, Urobilinogen, Bilirubin, Glucose, Protein, Blood, Specific Gravity and pH in/of human urine.

And the URIT 12FA Urine Reagent Strips read by URIT UC-1800 Automatic Urine Analyzer is safe, effective and such is substantially equivalent to the Mission® Urinalysis Reagent Strips (Microalbumin/Creatinine) read by the Mission® U120 Ultra Urine Analyzer(K142391) currently sold on the U.S. market for professional use at point-of-care locations in detecting Microalbumin and Creatinine in human urine.

And the URIT UC-1800 Automatic Urine Analyzer is safe, effective and such is substantially equivalent to the AUTION MAX AX-4030 Urinalysis System (K093098) currently sold on the U.S. market for professional use in detecting specific gravity, turbidity and color of human urine.