

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

A. 510(k) Number:

k142543

B. Purpose for Submission:

New device

C. Measurand:

Glucose, Bilirubin, Ketone (Acetoacetic Acid), Specific Gravity, pH, Blood, Protein, Urobilinogen, Leukocytes, Ascorbic Acid and Nitrite

D. Type of Test:

Semi-quantitative and qualitative urinalysis

E. Applicant:

Acon Laboratories Inc.

F. Proprietary and Established Names:

Mission® Urinalysis Reagent Strips
Mission U120 Ultra Urine Analyzer
Mission Liquid Urine Controls
Mission Liquid Diptube Urine Controls

G. Regulatory Information:

Regulation Description	Product Code	Device Class	Regulation
Occult blood test	JIO	II	21 CFR § 864.6550
Urinary glucose (non-quantitative) test system	JIL	II	21 CFR § 862.1340
Urinary protein or albumin (non-quantitative) test system	JIR	I	21 CFR § 862.1645
Urinary bilirubin and its conjugates (non-quantitative) test system	JJB	I	21 CFR § 862.1115
Ketones (non-quantitative) test system	JIN	I	21 CFR § 862.1435
Leukocyte peroxidase test	LJX	I	21 CFR § 864.7675
Nitrite (non-quantitative) test system	JMT	I	21 CFR § 862.1510
Urinary pH (non-quantitative) test system	CEN	I	21 CFR § 862.1550
Refractometer for clinical use (specific gravity)	JRE	I	21 CFR § 862.2800

Regulation Description	Product Code	Device Class	Regulation
Urinary urobilinogen (non-quantitative) test system	CDM	I	21 CFR § 862.1785
Ascorbic acid test system	JMA	I	21 CFR § 862.1095
Quality control material (assayed and unassayed)	JJW	I, reserved	21 CFR § 862.1660
Automated urinalysis system	KQO	I	21 CFR § 862.2900□

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

H. Intended Use:

1. Intended use(s):

Refer to indications for use below.

2. Indication(s) for use:

The Mission® U120 Ultra Urine Analyzer is intended for use in conjunction with the Mission® Urinalysis Reagent Strips for the semi-quantitative detection of the following analytes in urine: glucose, bilirubin, ketone (acetoacetic acid), specific gravity, pH, blood, protein, urobilinogen, leukocytes and ascorbic acid as well as the qualitative detection of nitrite.

The instrument is intended for point-of-care, *in vitro* diagnostic use only. The measurement can be used in general evaluation of health, and aids in the diagnosis and monitoring of metabolic or systemic diseases that affect kidney function, endocrine disorders and diseases or disorders of the urinary tract. It is intended for professional use only.

The Mission® Liquid Urine Controls and Mission® Liquid Diptube Urine Controls are assayed urine controls, intended for use in validating the precision of analyzer reading of urinalysis for one or more of the following analytes: ascorbic acid, glucose, bilirubin, ketone (acetoacetic acid), specific gravity, blood, pH, protein, urobilinogen, nitrite and leukocytes. It is intended for professional *in vitro* diagnostic use only.

3. Special conditions for use statement(s):

For prescription use only.

For point-of-care use.

4. Special instrument requirements:

Mission® U120 Ultra Urine Analyzer.

I. Device Description:

The Mission® U120 Ultra Urine Analyzer is a reflectance photometer that analyzes the intensity and color of light reflected from the reagent areas of a urinalysis reagent strip. Mission® U120 Ultra Urine Analyzer also features data management and report generation capabilities. The analyzer is capable of adjusting specific gravity results based on the measured urinary pH to account for variance in ionic concentrations.

The analyzer is for use with the Mission® Urinalysis Reagent Strips.

The Mission Liquid Urine Control and Mission Liquid Diptube Urine Control are prepared from simulated human urine with purified chemicals, constituents of animal origin, preservatives and stabilizers. The controls are available in two levels, ready to use liquid format packaged in dropper bottles (Mission Liquid Urine Control) or in diptube containers (Mission Liquid Diptube Urine Control).

J. Substantial Equivalence Information:

1. Predicate device name(s):

ACON Urinalysis Reagent Strips, ACON U120 Urine Analyzer
Mission Liquid Urine Control, Mission Liquid Diptube Urine Control

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

k070929
k103387

3. Comparison with predicate:

Mission U120 Ultra Urine Analyzer

Similarities		
Item	Mission® Urinalysis Reagent Strips, Mission® U120 Ultra Urine Analyzer, Candidate Device	ACON Urinalysis Reagent Strips, ACON U120 Urine Analyzer, Predicate (K070929)
Intended Use	Automated urine chemistry analyzer for the in vitro measurement of urine chemistry analytes.	Same
Methodology	Reflectance Photometer	Same
Principle	The Mission U120 Ultra Urine Analyzer measures the intensity of the light reflected from the reagent areas of a urinalysis reagent strip.	Same
Chemistry	Mission® Urinalysis	Same

Similarities		
Item	Mission® Urinalysis Reagent Strips, Mission® U120 Ultra Urine Analyzer, Candidate Device	ACON Urinalysis Reagent Strips, ACON U120 Urine Analyzer, Predicate (K070929)
	Reagent Strips (k061559)	
Analytes Detected	Leukocytes, Nitrite, blood (Occult), Glucose, Protein, Ketone, Specific Gravity, pH, Bilirubin, Urobilinogen and Ascorbic Acid.	Same
Strip Incubation Time	One minute	Same
Available Languages on the Screen	English and Spanish	Same
Analyzer Operating Conditions	0-40°C (32-104°F); ≤85% Relative Humidity (non-condensing).	Same
Line Leakage Current	<0.5mA	Same

Differences		
Item	Mission® Urinalysis Reagent Strips with Mission® U120 Ultra Urine Analyzer, Candidate Device	ACON Urinalysis Reagent Strips with ACON U120 Urine Analyzer, Predicate (K070929)
Detection Method	The Mission® U120 Ultra Urine Analyzer utilizes a CMOS image sensor to measure the intensity of light.	The ACON U120 Urine Analyzer utilizes a photodiode to measure the intensity of light.
Throughput	Single Test Mode: 55 tests/hour. Continuous Test Mode: 120 tests/hour.	Single Test Mode: 60 tests/hour. Continuous Test Mode: 120 tests/hour.
Memory	Last 2000 test results.	Last 500 test results.
PC Port	Standard RS232C Port (cable not included), USB Port (cable not included); (Not connect to PC) Bluetooth Wireless.	Standard RS232C Port (cable not included).
Capabilities	Internal thermal printer, Barcode reader Connector, External printer (optional), Barcode reader (optional),	Internal heat sensitive printer (included), 25 Pin Parallel External Printer Port (not included), and

Differences		
Item	Mission® Urinalysis Reagent Strips with Mission® U120 Ultra Urine Analyzer, Candidate Device	ACON Urinalysis Reagent Strips with ACON U120 Urine Analyzer, Predicate (K070929)
	and RJ45 Ethernet (optional).	External printer (optional).
Power Source	6 AA batteries with 100 tests/6 new batteries; 100- 240 VAC (adapter), (50-60 Hz ± 1HZ).	220 Volts AC (±10%), 50 Hz (±1); 110 Volts AC (±10%), 60 Hz (±1); 110-230 Volts AC, 50/60 Hz.
Optimum Strip Operating Conditions	15-30°C (59-86°F); 20-80% Relative Humidity (non-condensing).	15-30°C (59-86°F); ≤75% Relative Humidity (non-condensing).
User Interface	Touch Screen based UI.	MKB Key based UI.
Weight	≤1.66 kg (3.65 lbs.) without batteries or power supply.	2.6 Kg (5.73 lbs.)
Dimensions (L x W x H)	26.0 (L) x 15.0 (W) x 17.5 (H) cm.	27.1 (L) x 26.5 (W) x 14.6 (H) cm.
Display Dimensions (L x W)	Large touch screen Color LCD, TFT 640x480, 11.7 (W) x 8.8 (H) cm.	240 x 128 blue and white, 10.6 (W) x 2.8 (H) cm.

Mission Liquid Urine Control, Mission Liquid Diptube Urine Control

Similarities		
Item	Mission® Liquid Urine Controls, Mission® Liquid Diptube Urine Controls, Candidate Device	Mission® Liquid Urine Controls, Mission® Liquid Diptube Urine Controls, Predicate (K103387)
Indications for Use	For use as an assayed quality control urine to monitor the precision of urinalysis test procedures for the analytes listed in the package insert.	Same
Levels	2	Same
Form	Liquid	Same
Analytes	Glucose, bilirubin, ketone (acetoacetic acid), specific	Same

Similarities		
Item	Mission® Liquid Urine Controls, Mission® Liquid Diptube Urine Controls, Candidate Device	Mission® Liquid Urine Controls, Mission® Liquid Diptube Urine Controls, Predicate (K103387)
	gravity, blood, pH, protein, urobilinogen, nitrite, leukocytes, and ascorbic acid	
Storage	2 to 8°C	Same
Open Vial	24 months at 2-8°C 30 Days at 15-30°C	Same
Packaging Configuration	Dropper, Diptube	Same
Shelf Life	24 months at 2-8°C	Same

Differences		
Item	Mission® Liquid Urine Controls, Mission® Liquid Diptube Urine Controls, Candidate Device	Mission® Liquid Urine Controls, Mission® Liquid Diptube Urine Controls, Predicate (K103387)
Test system	The Mission® Liquid Urine Control and Mission® Liquid Diptube Urine Control are for use with the Mission® Urinalysis Reagent Strips and Mission U120 Ultra Urine Analyzer	The Mission® Liquid Urine Control and Mission® Liquid Diptube Urine Control are for use with the Mission® Urinalysis Reagent Strips and Mission U120 Urine Analyzer (K070929)

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

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

EN 61326-1:2006 Class A - Electrical Equipment for Measurement, Control and Laboratory Use - EMC Requirements. General Requirements.

EN ISO 14971:2007 - Medical Devices - Application of Risk Management to Medical Devices.

L. Test Principle:

The Mission® U120 Ultra Urine Analyzer is a reflectance photometer that analyzes the intensity and color of light reflected from the reagent areas of a urinalysis reagent strip. Using a light emitting diode (LED) as the light source and a CMOS image sensor as a light sensor, the optical system reads the color change in the urine test strips after a sample is applied.

The Mission® U120 Ultra Urine Analyzer is used in conjunction with the Mission® Urinalysis Reagent Strips and can detect qualitatively and/or semi-quantitatively the following analytes in urine: glucose, bilirubin, ketone (acetoacetic acid), specific gravity, pH, blood, protein, urobilinogen, leukocytes and ascorbic acid as well as the qualitative detection of nitrite. The chemical reactions between the analytes in the urine and each test pad on the Mission Urinalysis Reagent Strips that causes a change in color are described below:

Ascorbic acid: This test involves decolorization of Tillmann's reagent. The presence of ascorbic acid causes the color of the test field to change from blue-green to orange.

Glucose: This test is based on the enzymatic reaction that occurs between glucose oxidase, peroxidase and chromogen. Glucose is first oxidized to produce gluconic acid and hydrogen peroxide in the presence of glucose oxidase. The hydrogen peroxide reacts with potassium iodide chromogen in the presence of peroxidase. The extent to which the chromogen is oxidized determines the color which is produced, ranging from green to brown.

Bilirubin: This test is based on azo-coupling reaction of bilirubin with diazotized dichloroaniline in a strongly acidic medium. Varying bilirubin levels will produce a pinkish-tan color proportional to its concentration in urine.

Ketone: This test is based on ketones reacting with nitroprusside and acetoacetic acid to produce a color change ranging from light pink for negative results to a darker pink or purple color for positive results.

Specific Gravity: This test is based on the apparent pKa change of certain pretreated polyelectrolytes in relation to ionic concentration. In the presence of an indicator, colors range from deep blue-green in urine of low ionic concentration to green and yellow-green in urine of increasing ionic concentration.

Blood: This test is based on the peroxidase-like activity of hemoglobin which catalyzes the reaction of diisopropylbenzene dihydroperoxide and 3,3',5,5'-tetramethylbenzidine. The resulting color ranges from light orange to dark green.

pH: This test is based on a double indicator system which gives a broad range of colors covering the entire urinary pH range. Colors range from orange to yellow and green to blue.

Protein: This reaction is based on the phenomenon known as the "protein error" of pH indicators where an indicator that is highly buffered will change color in the presence of proteins (anions) as the indicator releases hydrogen ions to the protein. At a constant pH, the development of any green color is due to the presence of protein. Colors range from yellow to yellow-green for negative results and green to green-blue for positive results.

Urobilinogen: This test is based on a modified Ehrlich reaction between p-diethylaminobenzaldehyde and urobilinogen in strongly acidic medium to produce a pink color. Urobilinogen is one of the major compounds produced in heme synthesis and is a normal substance in urine.

Nitrite: This test depends upon the conversion of nitrate to nitrite by the action of Gram negative bacteria in the urine. In an acidic medium, nitrite in the urine reacts with p-arsanilic acid to form a diazonium compound. The diazonium compound in turn couples with 1N-(1-naphthyl) ethylenediamine to produce a pink color.

Leukocytes: This test reveals the presence of granulocyte esterases. The esterases cleave a derivatized pyrazole amino acid ester to liberate derivatized hydroxyl pyrazole. This pyrazole then reacts with a diazonium salt to produce a beige-pink to purple color.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

In-house Precision Study:

The precision of the Mission U120 Ultra Urine Analyzer used with the Mission Urinalysis Reagent Strips was evaluated using control solutions at level 1 (negative), level 2 (low analyte concentration) and level 3 (high analyte concentration). The target concentration of the analytes in each control solution was confirmed using previously cleared methods. The total precision of the Mission U120 Ultra Urine Analyzer was evaluated by testing each control solution was tested by two operators with two lots of strip in duplicate per run, two runs each day for 20 days on two Mission U120 Ultra Urine analyzers. A total of 160 strips were used for each level control solution tested (2 strips x 2 run x 20 days x 2 operators/analyzers/strip lots = 160 tests per control). The repeatability of the Mission U120 Ultra Urine Analyzer was evaluated by testing each level control solution by three operators on three analyzers in replicates of 20 per run per day with three lots of strip for one day. A total of 180 strips were used for each level control solution tested (20 strips x 3 strip lots x 1 day x 3 operators/analyzers = 180 tests per control). The results from the in-house precision evaluation are summarized below:

Analyte Levels Tested:

Analyte	Target Concentrations		
	Level 1	Level 2	Level 3
Ascorbic acid	0 mg/dL	10 mg/dL	40 mg/dL
Glucose	0 mg/dL	100 mg/dL	1000 mg/dL
Bilirubin	0 mg/dL	1 mg/dL	4 mg/dL
Ketone	0 mg/dL	5 mg/dL	80 mg/dL
Specific gravity	1.000	1.015	1.030

Analyte	Target Concentrations		
	Level 1	Level 2	Level 3
Blood (erythrocytes)	Negative (0 Ery/ μ L)	Trace (15 Ery/ μ L)	3+ (500 Ery/ μ L)
pH	5.0	7.0	9.0
Protein	0 mg/dL	15 mg/dL	300 mg/dL
Urobilinogen	0 mg/dL	2 mg/dL	8 mg/dL
Nitrite	0 mg/dL	0.05 mg/dL	0.1 mg/dL
Leukocyte	Negative (0 cells/ μ L)	Trace (15 cells/ μ L)	3+ (500 cells/ μ L)

Results Summary:

Control Level 1:

Analyte	Total Precision (N = 160)		Repeatability (N = 180)	
	Exact match	Match within ± 1 color block	Exact match	Match within ± 1 color block
Ascorbic acid	100% (160/160)	100% (160/160)	100% (180/180)	100% (180/180)
Glucose	100% (160/160)	100% (160/160)	100% (180/180)	100% (180/180)
Bilirubin	100% (160/160)	100% (160/160)	100% (180/180)	100% (180/180)
Ketone	100% (160/160)	100% (160/160)	100% (180/180)	100% (180/180)
Specific gravity	95.0% (152/160)	100% (160/160)	95.6% (172/180)	100% (180/180)
Blood (erythrocytes)	100% (160/160)	100% (160/160)	100% (180/180)	100% (180/180)
pH	97.5% (156/160)	100% (160/160)	97.2% (175/180)	100% (180/180)
Protein	100% (160/160)	100% (160/160)	100% (180/180)	100% (180/180)
Urobilinogen	100% (160/160)	100% (160/160)	100% (180/180)	100% (180/180)
Nitrite	100% (160/160)	100% (160/160)	100% (180/180)	100% (180/180)
Leukocyte	100% (160/160)	100% (160/160)	100% (180/180)	100% (180/180)

Control Level 2:

Analyte	Total Precision (N = 120)		Repeatability (N = 180)	
	Exact match	Match within ± 1 color block	Exact match	Match within ± 1 color block
Ascorbic acid	96.9% (155/160)	100% (160/160)	97.8% (176/180)	100% (180/180)

Analyte	Total Precision (N = 120)		Repeatability (N = 180)	
	Exact match	Match within ± 1 color block	Exact match	Match within ± 1 color block
Glucose	98.1% (157/160)	100% (160/160)	96.7% (174/180)	100% (180/180)
Bilirubin	97.5% (156/160)	100% (160/160)	97.2% (175/180)	100% (180/180)
Ketone	98.1% (157/160)	100% (160/160)	97.2% (175/180)	100% (180/180)
Specific gravity	95.6% (153/160)	100% (160/160)	92.2% (166/180)	100% (180/180)
Blood (erythrocytes)	98.8% (158/160)	100% (160/160)	95.6% (172/180)	100% (180/180)
pH	96.9% (155/160)	100% (160/160)	93.9% (169/180)	100% (180/180)
Protein	96.9% (155/160)	100% (160/160)	97.2% (175/180)	100% (180/180)
Urobilinogen	97.5% (156/160)	100% (160/160)	95.6% (172/180)	100% (180/180)
Nitrite	100% (160/160)	100% (160/160)	100% (180/180)	100% (180/180)
Leukocyte	99.4% (159/160)	100% (160/160)	98.3% (177/180)	100% (180/180)

Control Level 3:

Analyte	Total Precision (N = 120)		Repeatability (N = 180)	
	Exact match	Match within ± 1 color block	Exact match	Match within ± 1 color block
Ascorbic acid	100% (160/160)	100% (160/160)	98.9% (178/180)	100% (180/180)
Glucose	98.8% (158/160)	100% (160/160)	93.3% (168/180)	100% (180/180)
Bilirubin	98.1% (157/160)	100% (160/160)	97.2% (175/180)	100% (180/180)
Ketone	96.3% (154/160)	100% (160/160)	97.8% (176/180)	100% (180/180)
Specific gravity	94.4% (151/160)	100% (160/160)	97.8% (176/180)	100% (180/180)
Blood (erythrocytes)	99.4% (159/160)	100% (160/160)	96.7% (174/180)	100% (180/180)
pH	98.1% (157/160)	100% (160/160)	93.9% (169/180)	100% (180/180)
Protein	100% (160/160)	100% (160/160)	98.9% (178/180)	100% (180/180)
Urobilinogen	98.1% (157/160)	100% (160/160)	97.8% (176/180)	100% (180/180)
Nitrite	100% (160/160)	100% (160/160)	100% (180/180)	100% (180/180)
Leukocyte	98.1% (157/160)	100% (160/160)	97.8% (176/180)	100% (180/180)

Point-of-Care (POC) Precision Study:

The precision of the Mission® U120 Ultra Urine Analyzer at point-of-care (POC) sites was evaluated using control solutions at level 1 (negative), level 2 (low) and level 3 (high). Control solutions were prepared by spiking each analyte in negative urine pool to the target concentrations shown in the table below. The concentrations of the analytes were confirmed using previously cleared methods. The three level control solutions were dispensed in to different containers and were labeled randomly with coded numbers. Three set of coded samples were sent to three POC sites (in U.S.) for testing by three POC operators at each site. Each sample was tested once per run, two runs per day for 20 days (N = 40 testing per sample). The results from the point-of-care precision study are summarized below.

Analyte Levels Tested:

Analyte	Target Concentrations		
	Level 1	Level 2	Level 3
Ascorbic acid	0 mg/dL	10 mg/dL	40 mg/dL
Glucose	0 mg/dL	250 mg/dL	1000 mg/dL
Bilirubin	0 mg/dL	1 mg/dL	4 mg/dL
Ketone	0 mg/dL	5 mg/dL	80 mg/dL
Specific gravity	1.005	1.015	1.030
Blood (erythrocytes)	Negative (0Ery/ μ L)	Trace (15Ery/ μ L)	3+ (500 Ery/ μ L)
pH	5.0	6.0	7.0
Protein	0 mg/dL	30 mg/dL	300 mg/dL
Urobilinogen	0 mg/dL	2 mg/dL	8 mg/dL
Nitrite	0 mg/dL	+	N/A
Leukocyte	Negative (0cells/ μ L)	1+ (70 cells/ μ L)	3+ (500cells/ μ L)

Results Summary:

POC Site 1:

Analyte	Control Level 1		Control Level 2		Control Level 3	
	Exact match	Match within ± 1 color block	Exact match	Match within ± 1 color block	Exact match	Match within ± 1 color block
Ascorbic	100%	100%	100%	100%	100%	100%

Analyte	Control Level 1		Control Level 2		Control Level 3	
	Exact match	Match within ± 1 color block	Exact match	Match within ± 1 color block	Exact match	Match within ± 1 color block
acid	(40/40)	(40/40)	(40/40)	(40/40)	(40/40)	(40/40)
Glucose	100% (40/40)	100% (40/40)	92.5 % (37/40)	100% (40/40)	97.5% (39/40)	100% (40/40)
Bilirubin	100% (40/40)	100% (40/40)	100% (40/40)	100% (40/40)	100% (40/40)	100% (40/40)
Ketone	100% (40/40)	100% (40/40)	97.5% (39/40)	100% (40/40)	100% (40/40)	100% (40/40)
Specific gravity	95.0% (38/40)	100% (40/40)	100% (40/40)	100% (40/40)	100% (40/40)	100% (40/40)
Blood	100% (40/40)	100% (40/40)	100% (40/40)	100% (40/40)	100% (40/40)	100% (40/40)
pH	100% (40/40)	100% (40/40)	92.5 % (37/40)	100% (40/40)	92.5 % (37/40)	100% (40/40)
Protein	100% (40/40)	100% (40/40)	95.0% (38/40)	100% (40/40)	100% (40/40)	100% (40/40)
Urobilinogen	100% (40/40)	100% (40/40)	97.5% (39/40)	100% (40/40)	95.0% (38/40)	100% (40/40)
Nitrite	100% (40/40)	100% (40/40)	100% (40/40)	100% (40/40)	N/A	N/A
Leukocyte	100% (40/40)	100% (40/40)	97.5% (39/40)	100% (40/40)	100% (40/40)	100% (40/40)

POC Site 2:

Analyte	Control Level 1		Control Level 2		Control Level 3	
	Exact match	Match within ± 1 color block	Exact match	Match within ± 1 color block	Exact match	Match within ± 1 color block
Ascorbic acid	100% (40/40)	100% (40/40)	97.5% (39/40)	100% (40/40)	97.5% (39/40)	100% (40/40)
Glucose	100% (40/40)	100% (40/40)	100% (40/40)	100% (40/40)	100% (40/40)	100% (40/40)

Analyte	Control Level 1		Control Level 2		Control Level 3	
	Exact match	Match within ± 1 color block	Exact match	Match within ± 1 color block	Exact match	Match within ± 1 color block
Bilirubin	100% (40/40)	100% (40/40)	100% (40/40)	100% (40/40)	97.5% (39/40)	100% (40/40)
Ketone	100% (40/40)	100% (40/40)	100% (40/40)	100% (40/40)	100% (40/40)	100% (40/40)
Specific gravity	92.5 % (37/40)	100% (40/40)	97.5% (39/40)	100% (40/40)	97.5% (39/40)	100% (40/40)
Blood	100% (40/40)	100% (40/40)	95.0% (38/40)	100% (40/40)	100% (40/40)	100% (40/40)
pH	100% (40/40)	100% (40/40)	100% (40/40)	100% (40/40)	92.5 % (37/40)	100% (40/40)
Protein	100% (40/40)	100% (40/40)	97.5% (39/40)	100% (40/40)	100% (40/40)	100% (40/40)
Urobilinogen	100% (40/40)	100% (40/40)	100% (40/40)	100% (40/40)	95.0% (38/40)	100% (40/40)
Nitrite	100% (40/40)	100% (40/40)	100% (40/40)	100% (40/40)	N/A	N/A
Leukocyte	100% (40/40)	100% (40/40)	97.5% (39/40)	100% (40/40)	100% (40/40)	100% (40/40)

POC Site 3:

Analyte	Control Level 1		Control Level 2		Control Level 3	
	Exact match	Match within ± 1 color block	Exact match	Match within ± 1 color block	Exact match	Match within ± 1 color block
Ascorbic acid	100% (40/40)	100% (40/40)	100% (40/40)	100% (40/40)	100% (40/40)	100% (40/40)
Glucose	100% (40/40)	100% (40/40)	100% (40/40)	100% (40/40)	100% (40/40)	100% (40/40)
Bilirubin	100% (40/40)	100% (40/40)	100% (40/40)	100% (40/40)	100% (40/40)	100% (40/40)
Ketone	100% (40/40)	100% (40/40)	100% (40/40)	100% (40/40)	92.5 % (37/40)	100% (40/40)

Analyte	Control Level 1		Control Level 2		Control Level 3	
	Exact match	Match within ± 1 color block	Exact match	Match within ± 1 color block	Exact match	Match within ± 1 color block
Specific gravity	92.5 % (37/40)	100% (40/40)	100% (40/40)	100% (40/40)	100% (40/40)	100% (40/40)
Blood	100% (40/40)	100% (40/40)	97.5% (39/40)	100% (40/40)	100% (40/40)	100% (40/40)
pH	100% (40/40)	100% (40/40)	92.5 % (37/40)	100% (40/40)	95.0% (38/40)	100% (40/40)
Protein	100% (40/40)	100% (40/40)	100% (40/40)	100% (40/40)	100% (40/40)	100% (40/40)
Urobilinogen	100% (40/40)	100% (40/40)	100% (40/40)	100% (40/40)	100% (40/40)	100% (40/40)
Nitrite	100% (40/40)	100% (40/40)	100% (40/40)	100% (40/40)	N/A	N/A
Leukocyte	100% (40/40)	100% (40/40)	97.5% (39/40)	100% (40/40)	100% (40/40)	100% (40/40)

Three POC Sites Combined:

Analyte	Control Level 1		Control Level 2		Control Level 3	
	Exact match	Match within ± 1 color block	Exact match	Match within ± 1 color block	Exact match	Match within ± 1 color block
Ascorbic acid	100% (120/120)	100% (120/120)	99.2% (119/120)	100% (120/120)	99.2% (119/120)	100% (120/120)
Glucose	100% (120/120)	100% (120/120)	97.5% (117/120)	100% (120/120)	99.2% (119/120)	100% (120/120)
Bilirubin	100% (120/120)	100% (120/120)	100% (120/120)	100% (120/120)	99.2% (119/120)	100% (120/120)
Ketone	100% (120/120)	100% (120/120)	99.2% (119/120)	100% (120/120)	97.5% (117/120)	100% (120/120)
Specific gravity	93.3% (112/120)	100% (120/120)	99.2% (119/120)	100% (120/120)	99.2% (119/120)	100% (120/120)
Blood	100% (120/120)	100% (120/120)	97.5% (117/120)	100% (120/120)	100% (120/120)	100% (120/120)

Analyte	Control Level 1		Control Level 2		Control Level 3	
	Exact match	Match within ± 1 color block	Exact match	Match within ± 1 color block	Exact match	Match within ± 1 color block
pH	100% (120/120)	100% (120/120)	95.0% (114/120)	100% (120/120)	95.0% (114/120)	100% (120/120)
Protein	100% (120/120)	100% (120/120)	97.5% (117/120)	100% (120/120)	100% (120/120)	100% (120/120)
Urobilinogen	100% (120/120)	100% (120/120)	99.2% (119/120)	100% (120/120)	96.7% (116/120)	100% (120/120)
Nitrite	100% (120/120)	100% (120/120)	100% (120/120)	100% (120/120)	N/A	N/A
Leukocyte	100% (120/120)	100% (120/120)	98.3% (118/120)	100% (120/120)	100% (120/120)	100% (120/120)

b. Linearity/assay reportable range:

A study to evaluate the reportable range (percent recovery) for each analyte color block on the Mission® Urinalysis Reagent Strips was performed by measuring negative urine and negative urine spiked with known concentrations corresponding to the color blocks for each analyte on the test strip. The negative or expected value of each sample was confirmed using the previously cleared methods. Each sample was tested using three lots of strip, three strips per lot on three analyzers/operators for three days. A total of 81 strips were used for each analyte concentration tested (3 strips x 3 strip lots x 3 operators / analyzers x 3 days = 81 strips per sample). The percentages of exact block match of reported results at each analyte concentration were calculated and recorded.

The percent recovery for each analyte at each concentration block (N=81 per sample) is shown in the table below:

Analyte	Color Block Output Units (Reportable Range)		Concentration tested	Percent Exact Match
	Arbitrary	Conventional		
Ascorbic Acid	3+	40 mg/dL	40 mg/dL	100%
	2+	20 mg/dL	20 mg/dL	100%
	1+	10 mg/dL	10 mg/dL	100%
	-	0 mg/dL	0 mg/dL	100%
Glucose	3+	1000 mg/dL	1000 mg/dL	100%
	2+	500 mg/dL	500 mg/dL	100%
	1+	250 mg/dL	250 mg/dL	100%
	\pm	100 mg/dL	100 mg/dL	100%

Analyte	Color Block Output Units (Reportable Range)		Concentration tested	Percent Exact Match
	Arbitrary	Conventional		
	-	0 mg/dL	0 mg/dL	100%
Bilirubin	3+	4 mg/dL	4 mg/dL	100%
	2+	2 mg/dL	2 mg/dL	100%
	1+	1 mg/dL	1 mg/dL	100%
	-	0 mg/dL	0 mg/dL	100%
Ketone	3+	80 mg/dL	80 mg/dL	100%
	2+	40 mg/dL	40 mg/dL	100%
	1+	15 mg/dL	15 mg/dL	100%
	±	5 mg/dL	5 mg/dL	100%
	-	0 mg/dL	0 mg/dL	100%
Specific Gravity	1.000	1.000	1.000	97.5%
	1.005	1.005	1.005	95.1%
	1.010	1.010	1.010	97.5%
	1.015	1.015	1.015	96.3%
	1.020	1.020	1.020	95.1%
	1.025	1.025	1.025	96.3%
	1.030	1.030	1.030	95.1%
Blood	3+	200 Ery/μL	200 Ery/μL	100%
	2+	80 Ery/μL	80 Ery/μL	100%
	1+	25 Ery/μL	25 Ery/μL	100%
	±	10 Ery/μL	10 Ery/μL	100%
	-	0 Ery/μL	0 Ery/μL	100%
pH		5.0	5.0	98.8%
		5.5	5.5	97.5%
		6.0	6.0	96.3%
		6.5	6.5	96.3%
		7.0	7.0	97.5%
		7.5	7.5	97.5%
		8.0	8.0	95.1%
		8.5	8.5	96.3%
		9.0	9.0	96.3%
Protein	3+	300 mg/dL	300 mg/dL	100%
	2+	100 mg/dL	100 mg/dL	100%
	1+	30 mg/dL	30 mg/dL	100%
	±	15 mg/dL	15 mg/dL	100%
	-	0 mg/dL	0 mg/dL	100%
Urobilinogen	3+	8 mg/dL	8 mg/dL	100%
	2+	4 mg/dL	4 mg/dL	100%
	1+	2 mg/dL	2 mg/dL	100%

Analyte	Color Block Output Units (Reportable Range)		Concentration tested	Percent Exact Match
	Arbitrary	Conventional		
		±		
	-	0.2mg/dL	0.2mg/dL	100%
Nitrite	-	0.1 mg/dL	0.1 mg/dL	100%
	+	0 mg/dL	0 mg/dL	100%
Leukocyte	3+	500 Leu/μL	500 Leu/μL	100%
	2+	125 Leu/μL	125 Leu/μL	100%
	1+	70 Leu/μL	70 Leu/μL	100%
	±	15 Leu/μL	15 Leu/μL	100%
	-	0 Leu/μL	0 Leu/μL	100%

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

Traceability – The raw material for each analyte used for the two controls is purchased from supplier with a certificate of analysis and prepared gravimetrically to specific target analyte concentrations. The traceability chart provided by the sponsor is acceptable.

Value assignment - The Mission Liquid Urine Control and the Mission Liquid Diptube Urine Control (level 1 and 2) were value assigned by testing three lots of control on three Mission U120 Ultra Urine Analyzers using three lots of Mission Urinalysis Reagent Strips, for three consecutive days by three operators (N=243). The assigned reference value range is printed in the “Expected Values” sheet included with the package insert for each lot of urine controls. The target concentrations for the two control levels are summarized in the table below:

Urine Control format	Analyte	Target concentration for Control	
		Level 1	Level 2
Mission Liquid Urine Control / Mission Liquid Diptube Urine Control	Leukocyte	Negative	2+ (125 cells/μL)
	Nitrite	Negative	Positive
	Urobilinogen	Negative	3+ (8 mg/dL)
	Protein	Negative	3+ (300 mg/dL)
	pH	6.0	7.5
	Blood	Negative	3+ (200 ery/μL)
	Specific gravity	1.025	1.015
	Ketone	Negative	3+ (80 mg/dL)
	Bilirubin	Negative	3+ (4 mg/dL)
	Glucose	Negative	1+ (250 mg/dL)

Urine Control format	Analyte	Target concentration for Control	
		Level 1	Level 2
	Ascorbic acid	Negative	Negative

Stability of the Mission Liquid Urine Control and the Mission Liquid Diptube Urine Control (level 1 and 2) – The real time stability study protocol for the open vial storage stability and shelf-life, and the acceptance criteria for the two controls was reviewed and cleared under k103387. The two controls have a claimed shelf life of 24 months when stored at 2 to 8 °C. Open control vials are stable for 30 days when stored at 15 to 30 °C and for 24 months when stored at 2 to 8 °C.

Stability of the Mission Urinalysis Reagent Strips – The stability study protocol and acceptance criteria for the reagent strips was reviewed and found acceptable. Based on the accelerated and real time studies, the claimed shelf life is 24 months when stored at 2 to 8 °C or at room temperature (30 ± 3 °C). Open canister strips (opened 100 times) are stable for 98 days when stored at room temperature and 50 to 80% relative humidity conditions.

d. *Detection limit:*

The cutoff of the assay at each color block was validated by spiking or diluting a pooled urine sample with the stock solution of an analyte to achieve several concentration levels. Each sample was tested with three test strips on three analyzer by three operators, using three test strip lots for three days (3 strips x 3 operators/analyzers x 3 strip lots x 3 days = 81 tests). The cutoffs for each color block are defined as the lowest and highest concentrations of analyte tested at which over 50% of the results are positive for each color block.

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

Analyte	Color Block	Low Concentration cut-off	High Concentration cut-off
Ascorbic Acid	40 mg/dL	30 mg/dL	>40 mg/dL
	20 mg/dL	15 mg/dL	27.0 mg/dL
	10 mg/dL	5 mg/dL	13.5 mg/dL
	0 mg/dL	0 mg/dL	4.5 mg/dL
Glucose	1000 mg/dL	750 mg/dL	>1000 mg/dL
	500 mg/dL	375 mg/dL	675 mg/dL
	250 mg/dL	192.5 mg/dL	337.5mg/dL
	100 mg/dL	50 mg/dL	175 mg/dL
	0 mg/dL	0 mg/dL	45mg/dL
Bilirubin	4 mg/dL	3 mg/dL	>4 mg/dL
	2 mg/dL	1.5 mg/dL	2.7 mg/dL
	1 mg/dL	0.4 mg/dL	1.35 mg/dL

Analyte	Color Block	Low Concentration cut-off	High Concentration cut-off
	0 mg/dL	0 mg/dL	0.35 mg/dL
Ketone	80 mg/dL	60 mg/dL	> 80 mg/dL
	40 mg/dL	27.5 mg/dL	54 mg/dL
	15 mg/dL	11 mg/dL	24.75 mg/dL
	5 mg/dL	2.5 mg/dL	10 mg/dL
	0 mg/dL	0 mg/dL	2.25 mg/dL
Specific Gravity	1.000~1.030	1.000	1.030
Blood	200 Ery/ μ L	140 Ery/ μ L	>200 Ery/ μ L
	80 Ery/ μ L	52.5 Ery/ μ L	126 Ery/ μ L
	25 Ery/ μ L	12.5 Ery/ μ L	47.25 Ery/ μ L
	10 Ery/ μ L	5 Ery/ μ L	15.75 Ery/ μ L
	0 Ery/ μ L	0 Ery/ μ L	4.5 Ery/ μ L
pH	5.0~9.0	5.0	9.0
Protein	300 mg/dL	200 mg/dL	>300 mg/dL
	100 mg/dL	65 mg/dL	180 mg/dL
	30 mg/dL	22.5 mg/dL	58.5 mg/dL
	15 mg/dL	7.5 mg/dL	20.25 mg/dL
	0 mg/dL	0 mg/dL	6.75 mg/dL
Urobilinogen	8 mg/dL	6 mg/dL	>8 mg/dL
	4 mg/dL	3 mg/dL	5.4 mg/dL
	2 mg/dL	1.5 mg/dL	2.7 mg/dL
	1 mg/dL	0.6 mg/dL	1.35 mg/dL
	0.2mg/dL	0 mg/dL	0.54mg/dL
Nitrite	0.1 mg/dL	0.05mg/dL	>0.1 mg/dL
	0 mg/dL	0 mg/dL	0.045 mg/dL
Leukocyte	500 Leu/ μ L	312.5 Leu/ μ L	>500 Leu/ μ L
	125 Leu/ μ L	97.5 Leu/ μ L	281.25 Leu/ μ L
	70 Leu/ μ L	42.5 Leu/ μ L	87.75 Leu/ μ L
	15 Leu/ μ L	9 Leu/ μ L	38.25 Leu/ μ L
	0 Leu/ μ L	0 Leu/ μ L	8.25 Leu/ μ L

e. *Analytical specificity:*

To evaluate interferences, known amounts of potential interfering substances commonly found in human urine were added to pooled urine samples and tested using the Mission Urinalysis Reagent Strips and the Mission U120 Ultra Urine Analyzers. Ten normal fresh urines were pooled and confirmed to be negative for the eleven analytes. The pooled urine was spiked with the eleven analytes at the target concentrations listed in the table below. The concentration of each analyte in the

three level urine controls was confirmed with using previously cleared methods.

Analyte	Target Concentrations		
	Level 1	Level 2	Level 3
Ascorbic acid	0 mg/dL	10 mg/dL	40 mg/dL
Glucose	0 mg/dL	100 mg/dL	1000 mg/dL
Bilirubin	0 mg/dL	1 mg/dL	4 mg/dL
Ketone	0 mg/dL	5 mg/dL	80 mg/dL
Specific gravity	1.000	1.015	1.030
Blood (erythrocytes)	Negative (0 Ery/ μ L)	Trace (15 Ery/ μ L)	3+ (500 Ery/ μ L)
pH	5.0	7.0	9.0
Protein	0 mg/dL	15 mg/dL	300 mg/dL
Urobilinogen	0 mg/dL	2 mg/dL	8 mg/dL
Nitrite	0 mg/dL	0.05 mg/dL	0.1 mg/dL
Leukocyte	Negative (0 cells/ μ L)	Trace (15 cells/ μ L)	3+ (500 cells/ μ L)

The three level urine controls were spiked with the interfering substances. Three levels of each analyte and at least two (or more when needed) levels of interfering substance per analyte were evaluated in the study as per the CLSI EP7-A2 guideline. Each urine sample was tested with one strip per lot and one analyzer. A total of three strip lots and three analyzers (N = 9 testing per sample) were used for the study. Interference is defined when the testing result with spiked interfering substance is not the same color block as the expected result with the control solution with no interfering substance. No interference is defined when the testing result with spiked interfering substance is the same color block as the expected result with the control solution with no interfering substance.

Concentrations of the potentially interfering substances that will not have influence on the test results are shown below:

Potential Interfering Substance	Concentration Not Affecting Test
Albumin	≤ 150 mg/dL
Ascorbic Acid	≤ 20 mg/dL
Hemoglobin	≤ 10 mg/dL
Citric Acid	75 mg/dL
Bilirubin	170 mg/dL
Creatine	10 mg/dL
Lithium Acetoacetate	≤ 50 mg/dL
Ammonium Chloride	100 mg/dL
Calcium Chloride	275 mg/dL

Potential Interfering Substance	Concentration Not Affecting Test
Creatinine	600 mg/dL
Glucose	≤ 1000 mg/dL
Glycine	450 mg/dL
KCL	1500 mg/dL
NaCl	5500 mg/dL
Oxalic Acid	70 mg/dL
Sodium Acetate	25 mg/dL
Sodium Bicarbonate	1500 mg/dL
Sodium Nitrate	10 mg/dL
Sodium Nitrite	10 mg/dL
Sodium Phosphate	500 mg/dL
Uric Acid	150 mg/dL
Urea	4000 mg/dL
Riboflavin	10 mg/L
Theophylline	100 mg/L
Galactose	80 mg/dL
Fructose	100 mg/dL
Lactose	10 mg/dL
Leucocytes	2500 cells/μL
Blood	≤0.01%
Human Immunoglobulins	25 mg/dL

The following substances were shown to interfere with specific analyte results at the listed concentrations:

Reagent Pad	Interferent	Interferent Concentration	Mission U120 Ultra Urine Analyzer/Mission Urinalysis Reagent Strips Results
Glucose	Ascorbic acid	≥ 25 mg/dL	Falsely decreased results (-1 to -3 color block change)
	Ketone (acetoacetate)	≥ 100 mg/dL	Falsely decreased results (-1 color block change)
Bilirubin	Ascorbic acid	≥ 50 mg/dL	Falsely decreased results (-1 to -2 color block change)
	Blood	≥ 5%	Falsely increased results (+1 color block change)
Ketone	Blood	≥ 5%	Falsely increased results (+1 color block change)
Specific Gravity	Protein (albumin)	≥ 300 mg/dL	Falsely increased results (+1 to +2 color block change)

Reagent Pad	Interferent	Interferent Concentration	Mission U120 Ultra Urine Analyzer/Mission Urinalysis Reagent Strips Results
Blood	Ascorbic acid	≥ 50 mg/dL	Falsely decreased results (-1 to -4 color block change)
Urobilinogen	Blood	$\geq 5\%$	Falsely increased results (+1 color block change)
Protein	Hemoglobin	≥ 20 mg/dL	Falsely increased results (+1 to +4 color block change)
	Blood	$\geq 0.05\%$	Falsely increased results (+1 to +4 color block change)
Nitrite	Ascorbic acid	≥ 30 mg/dL	Falsely decreased results (positive to negative color block change)
	Blood	$\geq 1\%$	Falsely increased results (negative to positive color block change)
Leukocyte	Glucose	≥ 2000 mg/dL	Falsely decreased results (-1 to -2 color block change)
	Blood	$\geq 0.05\%$	Falsely increased results (+1 to +4 color block change)

pH Interference:

The sponsor performed an additional study to evaluate the effect of sample pH on the test results for the ten analytes in human urine. The study result shows that sample pH from 5.0 to 9.0 does not affect the test results for urobilinogen, ketone, bilirubin and glucose. Samples with pH greater than 8.0 affected the protein test resulting in a false high result, and the blood test resulting in a false low result. Samples with pH greater than 9.0 affected leukocyte and specific gravity tests giving falsely high results and affected nitrite and ascorbic acid tests giving falsely low results.

Specific Gravity Interference:

The sponsor performed an additional study to evaluate the effect of sample specific gravity on the test results for the ten analytes in human urine. The study result shows that sample specific gravity from 1.000 to 1.040 does not affect the test results for urobilinogen, pH, blood, ketone, bilirubin and ascorbic acid. Samples with specific gravity higher than 1.025 affected nitrite, protein and glucose tests giving false low results. Samples with specific gravity higher than 1.020 affected leukocyte test giving false low result.

The sponsor has included the effects from above interfering substances in the

labeling as limitations of the device.

f. Assay cut-off:

Not applicable.

2. Comparison studies:

a. *Method comparison with predicate device:*

Comparison studies were performed at five different POC sites to evaluate the performance of the Mission® Urinalysis Reagent strip read by the Mission® U120 Ultra Urine Analyzer compared to the performance of the predicate method, Mission® Urinalysis Reagent strip read by ACON U120 Urine Analyzer. A total of 120 patient urine specimens were randomly collected from patients at each of the three POC sites (combined total of 360 clinical specimens), and tested by three POC users at each site (total of nine users for all sites). In order to evaluate the performance of the candidate device over the entire measuring range of each analyte, additional samples, including contrived urine samples, were tested at two additional POC sites resulting in up to 468 samples evaluated at all sites. Results of the comparison study for the combined sites are shown in the tables below.

Leukocytes		ACON U120 Urine Analyzer					
		-	±	1+	2+	3+	Total
Mission U120 Ultra Urine Analyzer	-	285	2	0	0	0	287
	±	3	15	4	0	0	22
	1+	0	1	37	4	0	42
	2+	0	0	2	45	3	50
	3+	0	0	0	3	64	67
	Total	288	18	43	52	67	468
Agreement within same color block		99.0% (285/288)	83.3% (15/18)	86.0% (37/43)	86.5% (45/52)	95.5% (64/67)	
Agreement within ±1 color block		100.0% (288/288)	100.0% (18/18)	100.0% (43/43)	100.0% (52/52)	100.0% (67/67)	

Nitrite		ACON U120 Urine Analyzer		
		-	+	Total
Mission U120 Ultra Urine Analyzer	-	348	0	348
	+	0	103	103
	Total	348	103	451
Agreement within same color block		100.0% (348/348)	100.0% (103/103)	
Agreement within ±1 color block		100.0% (348/348)	100.0% (103/103)	

Urobilinogen		ACON U120 Urine Analyzer					
		-	±	1+	2+	3+	Total
Mission U120 Ultra Urine Analyzer	-	352	0	0	0	0	352
	±	1	23	2	0	0	26
	1+	0	2	13	1	0	16
	2+	0	0	1	10	2	13
	3+	0	0	0	2	17	19
	Total	353	25	16	13	19	426
Agreement within same color block		99.7% (352/353)	92.0% (23/25)	81.2% (13/16)	76.9% (10/13)	89.5% (17/19)	
Agreement within ±1 color block		100.0% (353/353)	100.0% (25/25)	100.0% (16/16)	100.0% (13/13)	100.0% (19/19)	

Protein		ACON U120 Urine Analyzer					
		-	±	1+	2+	3+	Total
Mission U120 Ultra Urine Analyzer	-	196	6	0	0	0	202
	±	8	81	2	0	0	91
	1+	0	5	51	3	0	59
	2+	0	0	4	60	2	66
	3+	0	0	0	4	46	50
	Total	204	92	57	67	48	468
Agreement within same color block		96.1% (196/204)	88.0% (81/92)	89.5% (51/57)	89.6% (60/67)	95.8% (46/48)	
Agreement within ±1 color block		100.0% (204/204)	100.0% (92/92)	100.0% (57/57)	100.0% (67/67)	100.0% (48/48)	

pH		ACON U120 Urine Analyzer									
		5.0	5.5	6.0	6.5	7.0	7.5	8.0	8.5	9.0	Total
Mission U120 Ultra Urine Analyzer	5.0	50	3	0	0	0	0	0	0	0	53
	5.5	4	70	6	0	0	0	0	0	0	80
	6.0	0	9	103	0	0	0	0	0	0	112
	6.5	0	0	9	30	8	0	0	0	0	47
	7.0	0	0	0	6	63	3	0	0	0	72
	7.5	0	0	0	0	1	28	3	0	0	32
	8.0	0	0	0	0	0	5	29	1	0	35
	8.5	0	0	0	0	0	0	2	17	0	19
	9.0	0	0	0	0	0	0	0	2	16	18
	Total	54	82	118	36	72	36	34	20	16	468
Agreement within same color block		92.6% (50/54)	85.4% (70/82)	87.3% (103/118)	83.3% (30/36)	87.5% (63/72)	77.8% (28/36)	85.3% (29/34)	85.0% (17/20)	100.0% (16/16)	
Agreement within ± 1 color block		100.0% (54/54)	100.0% (82/82)	100.0% (118/118)	100.0% (36/36)	100.0% (72/72)	100.0% (36/36)	100.0% (34/34)	100.0% (20/20)	100.0% (16/16)	

Blood		ACON U120 Urine Analyzer					
		-	\pm	1+	2+	3+	Total
Mission U120 Ultra Urine Analyzer	-	237	5	0	0	0	242
	\pm	1	70	5	0	0	76
	1+	0	1	38	6	0	45
	2+	0	0	0	45	8	53
	3+	0	0	0	3	49	52
	Total	238	76	43	54	57	468
Agreement within same color block		99.6% (237/238)	92.1% (70/76)	88.4% (38/43)	83.3% (45/54)	86.0% (49/57)	
Agreement within ± 1 color block		100.0% (238/238)	100.0% (76/76)	100.0% (43/43)	100.0% (54/54)	100.0% (57/57)	

Specific gravity		ACON U120 Urine Analyzer							Total
		1.000	1.005	1.010	1.015	1.020	1.025	1.030	
Mission U120 Ultra Urine Analyz er	1.000	23	3	0	0	0	0	0	26
	1.005	0	33	9	0	0	0	0	42
	1.010	0	4	87	5	0	0	0	96
	1.015	0	0	5	80	5	0	0	90
	1.020	0	0	0	10	78	7	0	95
	1.025	0	0	0	0	12	49	2	63
	1.030	0	0	0	0	0	6	50	56
	Total	23	40	101	95	95	62	52	468
Agreement within same color block		100.0% (23/23)	82.5% (33/40)	86.1% (87/101)	84.2% (80/95)	82.1% (78/95)	79.0% (49/62)	96.2% (50/52)	
Agreement within ±1 color block		100.0% (23/23)	100.0% (40/40)	100.0% (101/101)	100.0% (95/95)	100.0% (95/95)	100.0% (62/62)	100.0% (52/52)	

Ketone		ACON U120 Urine Analyzer					
		-	±	1+	2+	3+	Total
Mission U120 Ultra Urine Analyzer	-	350	0	0	0	0	350
	±	1	44	3	0	0	48
	1+	0	3	15	2	0	20
	2+	0	0	1	23	1	25
	3+	0	0	0	1	14	15
Total		351	47	19	26	15	458
Agreement within same color block		99.7% (350/351)	93.6% (44/47)	78.9% (15/19)	88.5% (23/26)	93.3% (14/15)	
Agreement within ±1 color block		100.0% (351/351)	100.0% (47/47)	100.0% (19/19)	100.0% (26/26)	100.0% (15/15)	

Bilirubin		ACON U120 Urine Analyzer				
		-	1+	2+	3+	Total
Mission U120 Ultra Urine Analyzer	-	353	0	0	0	353
	1+	1	49	1	0	51
	2+	0	1	19	2	22
	3+	0	0	1	23	24
	Total	354	50	21	25	450
Agreement within same color block		99.7% (353/354)	98.0% (49/50)	90.5% (19/21)	92.0% (23/25)	
Agreement within ±1 color block		100.0% (354/354)	100.0% (50/50)	100.0% (21/21)	100.0% (25/25)	

Glucose		ACON U120 Urine Analyzer					
		-	±	1+	2+	3+	Total
Mission U120 Ultra Urine Analyzer	-	316	0	0	0	0	316
	±	1	14	4	0	0	19
	1+	0	2	32	4	0	38
	2+	0	0	2	34	6	42
	3+	0	0	0	1	52	53
Total		317	16	38	39	58	468
Agreement within same color block		99.7% (316/317)	87.5% (14/16)	84.2% (32/38)	87.2% (34/39)	89.7% (52/58)	
Agreement within ±1 color block		100.0% (317/317)	100.0% (16/16)	100.0% (38/38)	100.0% (39/39)	100.0% (58/58)	

Ascorbic acid		ACON U120 Urine Analyzer				
		-	1+	2+	3+	Total
Mission U120 Ultra Urine Analyzer	-	203	9	0	0	212
	1+	12	104	7	0	123
	2+	0	9	59	5	73
	3+	0	0	5	55	60
	Total	215	122	71	60	468
Agreement within same color block		94.4% (203/215)	85.2% (104/122)	83.1% (59/71)	91.7% (55/60)	
Agreement within ±1 color block		100.0% (215/215)	100.0% (122/122)	100.0% (71/71)	100.0% (60/60)	

b. *Matrix comparison:*

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

3. Clinical studies:

a. *Clinical Sensitivity:*

Not applicable.

b. *Clinical specificity:*

Not applicable.

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

Not applicable.

4. Clinical cut-off:

Not applicable.

5. Expected values/Reference range:

Expected values are included in the strips instructions for use and shown in the table below:

Analyte	Expected Values
Urobilinogen	0.2-1 mg/dL
Bilirubin	Negative
Ketone	Negative
Blood	Negative
Protein	Negative or ±
Nitrite	Negative
Leukocytes	Negative
Glucose	Negative
Ascorbic Acid	0-200 mg/dL
Specific Gravity	1.000-1.035
pH	4.5-8.0

The above listed expected values are from the following references cited and discussed in detail in the package insert.

Yoder J, Adams EC, Free, AH. *Simultaneous Screening for Urinary Occult Blood, Protein, Glucose, and pH*. Amer. J. Med Tech. 31:285, 1965.

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

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

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

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

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.

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

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

Burtis CA, Ashwood ER. *Tietz Textbook of Clinical Chemistry 2nd Ed*. 2205, 1994.

N. Instrument Name:

Mission® U120 Ultra Urine Analyzer.

O. System Descriptions:

1. Modes of Operation:

Single Test Mode: 55 tests/hour.

Continuous Test Mode: 120 tests/hour.

Semi-automatic reading of Mission reagent strips on Mission U120 Ultra urine analyzer. Each reagent strip is single use and must be replaced with a new strip for additional readings. The labeling and user guide specify that the strips are for single use.

2. Software:

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

Yes or No

3. Specimen Identification:

The Patient ID is entered either manually using the keyboard or scanned using the barcode reader (Barcode ID).

4. Specimen Sampling and Handling:

It is recommended that collection of the urine is in a clean and dry container and testing is completed as soon as possible. The use of urine preservatives is not recommended. If testing cannot be done within an hour after voiding, the specimen should be refrigerated. The refrigerated specimen should be brought to room temperature before testing.

The labeling also warns as "Prolonged storage of unpreserved urine at room temperature may result in microbial proliferation with resultant changes in pH. A shift to alkaline pH may cause false positive results with the protein test area. Urine containing glucose may decrease in pH as organisms metabolize the glucose. Contamination of the urine specimen with skin cleansers containing chlorhexidine may affect protein (and to a lesser extent, specific gravity and bilirubin) test results."

5. Calibration:

The *Mission*® U120 Ultra Urine Analyzer performs an automatic calibration each time a test is run.

6. Quality Control:

Recommendations for quality control are described in the labeling. Additionally, the users should follow local, state and federal regulations.

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

A study to validate the pH versus specific gravity correction function (pH compensation) of the Mission U120 Ultra Urine analyzer. pH compensation corrects the effect of sample pH on the test results of specific gravity. The study evaluated the effect of sample pH (4.0, 4.5,

5.0, 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0, 9.5 and 10.0) on the sample specific gravity (1.000, 1.005, 1.010, 1.015, 1.020, 1.025 and 1.030) test results before and after pH compensation adjustment activated on the candidate analyzer. The results of the study are summarized below:

Results Before pH Compensation:

Before Correction		Specific Gravity by Refractometer						
		1.000	1.005	1.010	1.015	1.020	1.025	1.030
Specific gravity by Mission U120 Ultra Urine Analyzer	1.000	117	45					
	1.005		54	54				
	1.010		18	18	45			
	1.015			45	27	54	9	9
	1.020				36	18	45	18
	1.025				9	36	36	27
	1.030					9	27	63
Agreement with same block		40.66%						
Agreement with \pm one block		93.41%						

Results After pH Compensation:

After Correction		Specific Gravity by Refractometer						
		1.000	1.005	1.010	1.015	1.020	1.025	1.030
Specific gravity by Mission U120 Ultra Urine Analyzer	1.000	117						
	1.005		117					
	1.010			117				
	1.015				105			
	1.020				12	108		
	1.025					9	117	9
	1.030							108
Agreement with same block		96.34%						
Agreement with \pm one block		100.00%						

Above summary results show that the agreement versus expected value on the same block is increased by 55.68% and agreement versus expected value within \pm one block is increased by 6.59% after pH compensation is activated on the Mission U120 Ultra Urine Analyzer. The interference from the sample pH on the sample specific gravity test results is decreased with

application of pH compensation on the analyzer.

Q. Proposed Labeling:

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

R. Conclusion:

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