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

A. 510(k) Number:

k173327

B. Purpose for Submission:

New device

C. Measurand:

Measurement of the following in urine samples: glucose, blood, protein, pH, specific gravity, and nitrite

D. Type of Test:

Qualitative and semi-quantitative urinalysis

E. Applicant:

Healthy.io, Ltd.

F. Proprietary and Established Names:

DIP | U.S. Urine Analysis Test System

G. Regulatory Information:

1. Regulation section:

Name	Regulation	Product Code	Device Class
Urinary Glucose (non-quantitative) test system	21 CFR §862.1340	JIL	II
Occult blood test	21 CFR §864.6550	JIO	II
Urinary pH (non-quantitative) test	21 CFR §862.1550	CEN	I
Urinary protein or albumin (non-quantitative) test system	21 CFR §862.1645	JIR	I
Refractometer for clinical use	21 CFR §862.2800	JRE	I

Name	Regulation	Product Code	Device Class
Nitrite (non-quantitative) test system	21 CFR §862.1510	JMT	I

2. Panel:

   Chemistry (75), Hematology (81)

H. Intended Use:

1. Intended use(s):

   See Indication(s)s for use below.

2. Indication(s) for use:

   The DIP | U.S. Urine Analysis Test System consists of a smartphone application, a proprietary Color-Board, and Urinalysis Reagent Strips. It is intended for the semi-quantitative detection of the following analytes in urine: Glucose, Specific Gravity, Blood, pH and Protein, as well as the qualitative detection of Nitrite.

   The DIP | U.S. Urine Analysis Test System is intended for prescription home-use only, with results provided directly to the physician. The results can be used to guide patient management and care, and aid in the diagnosis and monitoring of metabolic or systemic diseases that affect kidney function and endocrine disorders. Physician interpretation of the results should be made in conjunction with the patient's other clinical information to determine if further confirmatory tests or consultations are necessary. Patients do not have access to the results at any point in the process.

3. Special conditions for use statement(s):

   For prescription home use only.

   For in vitro diagnostic use only.

4. Special instrument requirements:

   LG Nexus 5

I. Device Description:

The DIP | U.S. Urine Analysis Test System is comprised of the following components:
1. Urine Receptacle
2. A single, individually-wrapped Mission Urinalysis Reagent Strip U031-101 (ACON Laboratories Inc., K061559)
3. Color-Board

4. Smartphone App
5. Back-end, cloud-based server
6. User Manual

J. Substantial Equivalence Information:

1. Predicate device name(s):

   ACON Mission U500 Urinalysis System

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

   K111221

3. Comparison with predicate:

Similarities		
Item	Subject Device k173327 DIP | U.S. Urine Analysis Test System	Predicate Device K111221 ACON Mission U500 Urinalysis System
Intended Use	For the *in vitro* measurement of urine chemistry analytes.	Same
Sample Type	Human urine	Same
Measurement Principle	Reflectance	Same

Differences		
Item	Subject Device k173327 DIP | U.S. Urine Analysis Test System	Predicate Device K111221 ACON Mission U500 Urinalysis System
Reader	LG Nexus 5	The Mission U500 Urine Analyzer
Analytes	Glucose, Protein, pH, Blood, Nitrites, Specific Gravity	Glucose, Protein, pH, Blood, Nitrites, Specific Gravity Bilirubin, Urobilinogen, Ketones, Leukocytes,

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

- Clinical and Laboratory Standards Institute (CLSI) EP05-A3

Evaluation of Precision of Quantitative Measurement Procedures.

- CLSI EP06-A Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach.

- CLSI EP07-A2 Interference Testing in Clinical Chemistry.

- CLSI EP17-A2 Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline- Second Edition.

L. Test Principle:

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.

Protein: This test is based on the protein-error-of-indicators reaction. At a constant pH, the presence of protein causes a change in the color of the indicator to a cyan color.

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.

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 cumene-hydroperoxide and 3,3',5,5'-tetramethylbenzidine. The resulting color ranges from orange to green to dark blue.

Nitrites: This test is based on the Griess reaction. Nitrite reacts with sulfanilamide, followed by a diazo-coupling reaction to form a pink colored product.

The strip is scanned and analyzed using the mobile device running the app. The results are then sent directly to the prescriber.

M. Performance Characteristics (if/when applicable):

1. <u>Analytical performance:</u>

   a. *Precision/Reproducibility:*
   The Repeatability study was conducted at 3 sites. Each site had one user performing the tests using one Nexus phone, 3 lots of strips and 20 replicates/lot. Two levels of

urine controls were tested, the results are summarized in the tables below by site. A total of 3 phones (Nexus 5) were tested across 3 different sites by 3 different users (N=180).

Repeatability-Urine Level 1 – Negative

Analyte	level	Within Run % Agreement (Exact match) site 1	Within Run % Agreement (Exact match) site 2	Within Run % Agreement (Exact match) site 3	% Agreement (+/- 1 Color Block)	N Total
Nitrite	Negative	100% (60/60)	100% (60/60)	100% (60/60)	100% (180/180)	180
Protein	Negative	100% (60/60)	100% (60/60)	100% (60/60)	100% (180/180)	180
pH	6.0	98.3% (59/60)	96.7% (58/60)	100% (60/60)	100% (180/180)	180
Blood	Negative	100% (60/60)	100% (60/60)	100% (60/60)	100% (180/180)	180
Specific Gravity	1.01	96.7% (58/60)	100% (60/60)	100% (60/60)	100% (180/180)	180
Glucose	Negative	100% (60/60)	100% (60/60)	100% (60/60)	100% (180/180)	180

Repeatability-Urine Level 2 – High-Positive

Analyte	Level	Within Run %Agreement (Exact match) site 1	Within Run %Agreement (Exact match) site 2	Within Run %Agreement (Exact match) site 3	% Agreement (+/- 1 Color Block)	N (Total)
Nitrite	Positive	100% (60/60)	100% (60/60)	100% (60/60)	100% (180/180)	180
Protein	300 mg/dL	100% (60/60)	83.3%* (50/60)	98.3% (59/60)	100% (180/180)	180
pH	8.0	100% (60/60)	100% (60/60)	100% (60/60)	100% (180/180)	180
Blood	200 Ery/µl	100% (60/60)	100% (60/60)	100% (60/60)	100% (180/180)	180
Specific Gravity	1.03	100% (60/60)	100% (60/60)	100% (60/60)	100% (180/180)	180
Glucose	1000 mg/dL	100% (60/60)	100% (60/60)	100% (60/60)	100% (180/180)	180

* For the protein high positive control (300mg/dL), 83.3% of the results were 3+, 16.7% of the results were 2+.

The reproducibility study was conducted at three sites. Each site had one user performing the tests, using one phone, and 3 lots of strips. Three levels of urine controls were tested, with 1 replicate per run, two runs a day (morning and afternoon), for 20 days. A total of 3 Nexus 5 phones were used across the sites by 3 different users (N= 1 replicate x2 runs x 3 lots x 1 phone x20 days x3 operators/sites=360). The results are summarized in the below table.

Sample	Negative		Low positive		High positive	
	% Agreement within same block	% Agreement within +/- 1 block	% Agreement within same block	% Agreement within +/- 1 block	% Agreement within same block	% Agreement within +/- 1 block
Nitrite	100% (360/360)	100% (360/360)	100% (360/360)	100% (360/360)	100% (360/360)	100% (360/360)
Protein	100% (360/360)	100% (360/360)	99.4% (358/360)	100% (360/360)	88.3%* (318/360)	100% (360/360)
pH	94.4% (340/360)	100% (360/360)	99.4% (358/360)	100% (360/360)	98.6% (355/360)	100% (360/360)
Blood	100% (360/360)	100% (360/360)	97.2% (350/360)	100% (360/360)	100% (360/360)	100% (360/360)
Specific Gravity	98.9% (356/360)	100% (360/360)	99.2% (357/360)	100% (360/360)	100% (360/360)	100% (360/360)
Glucose	99.7% (359/360)	100% (360/360)	98.9% (356/360)	100% (360/360)	100% (360/360)	100% (360/360)

* For the protein high positive control (300mg/dL), 88.3% of the results were 3+, 11.7% of the results were 2+.

b. Linearity/assay reportable range:

The reportable range for each analyte was evaluated by measuring negative urine samples spiked with commercially available reagents. The concentrations were confirmed by the predicate device before being tested using the candidate device. Samples were measured by 3 operators, each operator used one phone, 3 lots of test strips in replicates of 10, for a total of 90 measurements per sample.

Nitrite				
Output	Block Cut-off	Expected Concentration	% Exact Match	% Within 1 color block
Negative	0 mg/dL	0-0.03 mg/dL	100	100
Positive	0.1 mg/dL	0.055-0.1 mg/dL	100	100

pH				
Output	Block Cut-off	Expected Concentration	% Exact Match	% Within 1 color block
5	5	5-5.2	98.89	100
5.5	5.5	5.4-5.6	100	100
6	6	5.8-6	100	100
6.5	6.5	6.4-6.6	100	100
7	7	6.8-7.2	90	100
7.5	7.5	7.4-7.6	100	100
8	8	7.8-8.2	100	100
8.5	8	8.4-8.6	100	100
9	9	8.8-9	100	100

Protein				
Output	Block Cut-off	Expected Concentration	% Exact Match	% Within 1 color block
Negative	0 mg/dL	0-11 mg/dL	100	100
Trace	15 mg/dL	13-20 mg/dL	97.78	100
1+	30 mg/dL	23-65 mg/dL	100	100
2+	100 mg/dL	81-156 mg/dL	93.33	100
3+	300 mg/dL	>192 mg/dL	100	100

Specific Gravity				
Output	Block Cut-off	Expected Concentration	% Exact Match	% Within 1 color block
1.000	1.000	1.000	98.89	100
1.005	1.005	1.002-1.006	100	100
1.010	1.010	1.008-1.010	97.78	100
1.015	1.015	1.014-1.016	92.22	100
1.020	1.020	1.018-1.02	98.89	100
1.025	1.025	1.024-1.026	100	100
1.030	1.030	1.028-1.03	100	100

Blood				
Output	Block Cut-off	Expected Concentration	% Exact Match	% Within 1 color block
Negative	0 Ery/µL	0-4 Ery/µL	100	100
Trace	10 Ery/µL	8-16 Ery/µL	92.22	100
1+	25 Ery/µL	22-47 Ery/µL	94.44	100
2+	80 Ery/µL	69-128 Ery/µL	100	100
3+	200 Ery/µL	176-240 Ery/µL	100	100

Glucose				
Output	Block Cut-off	Expected Concentration	% Exact Match	% Within 1 color block
Negative	0 mg/dL	0-40 mg/dL	100	100
Trace	100 mg/dL	80-160 mg/dL	97.78	100
1+	250 mg/dL	220-350 mg/dL	100	100
2+	500 mg/dL	450-700 mg/dL	97.78	100
3+	1000 mg/dL	900-1400 mg/dL	100	100

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

Traceability:
The sponsor did not describe any degree of traceability for the device.

d. *Detection limit:*
The sponsor validated the Limit of Detection by testing spiked or diluted urine samples with analyte concentrations just below, at, and above each cutoff for each color block. For pH and specific gravity, the sponsor determined the detection limits for the first two color blocks (i.e., 5.0 to 5.5 and 5.5 to 6.0 for pH and 1.000 to 1.005 and 1.005 to 1.010 for specific gravity). Each sample was tested in 6 replicates/per reagents test strip lot, using 3 lot of test strips (n=18), and one Nexus 5 phone. The Limit of Detection for each color block was defined as the lowest concentration at which at least 55% of the samples were positive. The results are summarized below: limits of detection are presented in the tables below:

Analyte	Negative to Trace	Trace to 1+	1+ to 2+	2+ to 3+
Blood	6 Ery/ uL	19 Ery/ uL	58 Ery/ uL	152 Ery/ uL
Glucose	60 mg / dL	190 mg / dL	400 mg / dL	800 mg / dL
Protein	12 mg / dL	24 mg / dL	72 mg / dL	180 mg / dL

Analyte	Negative to Positive
Nitrites	0.04 mg / dL

Analyte	5.0 to 5.5	5.5 to 6.0
pH	5.4	5.8

Analyte	1.000 to 1.005	1.005 to 1.010
SG	1.002	1.008

The results of the linearity and detection limit studies support the following range of values claimed by the sponsor:

Parameter (abbreviation)	Qualitative units	Semi-quantitative units
Nitrite (NIT)	- +	Neg Pos
Protein (PRO)	- ± 1+ 2+ 3+	Neg 15mg/dL 30mg/dL 100mg/dL 300mg/dL
pH	5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5	5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5
Blood (BLO)	- ± 1+ 2+ 3+	Neg 10 Ery/µL 25 Ery/µL 80 Ery/µL 200 Ery/µL
Specific Gravity (SG)	1.005 1.010 1.015 1.020 1.025 1.030	1.005 1.010 1.015 1.020 1.025 1.030

Parameter (abbreviation)	Qualitative units	Semi-quantitative units
Glucose (GLU)	- ± 1+ 2+ 3+	Neg 100 mg/dL 250 mg/dL 500 mg/dL 1000 mg/dL

e. *Analytical specificity:*

Urine samples (negative, low positive, high positive) were spiked with potential interferents at low and high concentrations as recommended by CLSI-EP7. The spiked samples were compared to a control sample without the interferents, and interference was defined as a change in output of more than 1 color block between spiked and un-spiked (control) samples. When interference was detected, further testing was conducted to identify the concentration at which interference was not observed. Each sample was tested using 2 lots of urine dip stick, 2 replicates per lot, using Nexus 5 phone.

The interferents and the highest concentrations tested are listed in the table below:

Interferent	Highest Concentration Tested (mg/dL)
Acetoacetic Acid	250
Albumin	1250
Ammonium Chloride	500
Ascorbic Acid	200
Unconjugated Bilirubin	85
Calcium Chloride	275
Citric Acid	75
Creatine	10
Creatinine	300
Fructose	100
Galactose	80
Glycine	450
Glucose	1250
Lactose	10

Interferent	Highest Concentration Tested (mg/dL)
Hemoglobin	550
KCl	1500
NaCl	2750
Oxalic Acid	70
Phenolphthalein	300
Riboflavin	10
Sodium Bicarbonate	375
Sodium Nitrate	10
Sodium Nitrite	10
Sodium Phosphate	500
Theophylline	100
Urea	2000
Sodium Mercaptoethane (MESNA)	530

The following table shows the substances which interfered with the subject device. Results are expressed as the lowest concentration of the interfering substance that exhibited interference and the resulting change in output of the color block (number of color block change and negative or positive change indicated in parentheses). These interferences are described in the physician compendium available only to the prescriber.

Analyte	Concentration of Substance at which interference was observed	Change in Color Output
Nitrite	Unconjugated Bilirubin (≥ 6.3 mg/dL) Hemoglobin (≥ 178 mg/dL)	False Positive Results (+2)
Protein	Unconjugated Bilirubin (≥ 27.6 mg/dL)	False Negative Results (-2)
	Hemoglobin (≥ 20.6 mg/dL)	False Positive Results (+2)

Analyte	Concentration of Substance at which interference was observed	Change in Color Output
Blood	MESNA (≥ 13.25 mg/dL) Unconjugated Bilirubin (≥ 75.44 mg/dL) Sodium Phosphate (≥ 275 mg/dL)	False Positive Results (+2)
pH	Oxalic Acid (≥ 38.5 mg/dL) Calcium Chloride (≥ 151.25 mg/dL) Citric Acid (≥ 41.25 mg/dL) Ascorbic Acid (≥ 87.5 mg/dL) Sodium Chloride (≥ 2131.25 mg/dL)	False Negative Results (-2)
	Sodium Bicarbonate (≥ 164 mg/dL) Sodium Phosphate (≥ 218 mg/dL)	False Positive Results (+2)
SG	Sodium Bicarbonate (≥ 375 mg/dL) Sodium Phosphate (≥ 500 mg/dL)	False Negative Results (-2)
	Oxalic Acid (≥ 70 mg/dL) Potassium Chloride (≥ 487 mg/dL) Calcium Chloride (≥ 182 mg/dL) Hemoglobin (≥ 550 mg/dL) Albumin (≥ 1250 mg/dL) Sodium Chloride (≥ 2131.25 mg/dL)	False Positive Results (+2)
Glucose	Ascorbic Acid (≥ 200 mg/dL)	False Negative Results (-2)

The following statements are provided in the lay user labeling:

Factors That May Interfere With the Test Results

Note: Some substances (i.e. medications, vitamins, and dietary supplements) may change the color of urine and interfere with the reactions on the dipstick, making the test results unreliable. These substances may include, for example: Ascorbic Acid (vitamin C), Riboflavin (vitamin B2), Phenazopyridine (Pyridium), Rifampin (Rifadin), Nitrofurantoin (Furadantin). Do not take the test if you are menstruating. If you have any questions or concerns consult your healthcare provider before performing the test.

f. Assay cut-off:

Not applicable.

2. Comparison studies:

a. Method comparison with predicate device:

The first study enrolled 429 subjects from two U.S. clinical sites. The number of spiked samples did not exceed 15% for each analyte for all bins combined. Subjects including males and females, all ethnicities, ranging from 18-80 years of age participated in the study. LG Nexus 5 phones were used to perform the study. Samples were analyzed comparing the results obtained by subject using the DIP | U.S. device and results of aliquots of the same samples measured by a laboratory professional using the predicate (ACON Mission U500 Urine Analyzer). Each sample was tested once using the candidate device, three times on the ACON 500 analyzer, and the most common result was used in the comparison. The results are summarized in the tables below.

Nitrite

Dip | U.S.		Predicate		
		Negative	Positive	Total
Negative	Count	250	1	251
Positive	Count	3	30	33
Total	Count	253	31	284
	%Exact Match	98.8%	96.8%	98.59%
	% +/- 1 color block	100%	100%	100%

Protein

Dip | U.S		Predicate					
		Negative	Trace	1+	2+	3+	Total
Neg	Count	156	8				164
Trace	Count	18	52	2			72
1+	Count	1	7	13	6		27
2+	Count				10		10
3+	Count					11	11
Total	Count	175	67	15	16	11	284
	%Exact Match	89.1%	77.6%	86.7%	62.5%	100%	85.21%
	% +/- 1 color block	99.4%	100%	100%	100%	100%	99.65%

pH

Dip | U.S.		Predicate								
		5.0	5.5	6.0	6.5	7.0	7.5	8.0	8.5	Total
5.0	Count	1	2							3
5.5	Count	3	48	13						64
6.0	Count		6	81	18	1				106
6.5	Count				27	8				35
7.0	Count					45	1	3		49
7.5	Count					4	4	8		16
8.0	Count						1	4		5
8.5	Count								5	6
Total	Count	4	56	94	45	58	6	15	5	284
	%Exact Match	25%	85.7%	86.2%	60%	77.6%	66.7%	26.7%	100%	75.7%
	% +/- 1 color block	100%	100%	100%	100%	98.2%	100%	80%	100%	98.59%*

*One sample that read as pH of 9 using the comparator method read as pH of 8.5 using the candidate method.

Specific Gravity

Dip | U.S.		Predicate						
		1.005	1.01	1.015	1.02	1.025	1.03	Total
1.005	Count	13	2					15
1.01	Count	19	28	5				52
1.015	Count	3	6	24	8			41
1.02	Count		1	10	63	13		87
1.025	Count				12	26	21	59
1.03	Count					4	26	30
Total	Count	35	37	39	83	43	47	284
	%Exact Match	37.1%	75.7%	61.5%	75.9%	60.5%	55.3%	63.38%
	% +/- 1 color block	91.4%	97.3%	100%	100%	100%	100%	98.59%

In a second study, 250 subjects who met the eligibility requirements were recruited from one clinical site to evaluate the accuracy of blood and glucose using the same

protocol as in the first study. A total of 289 samples were tested (250 neat samples and 39 spiked samples), and the results are summarized below:

Blood

Dip | U.S.		Predicate					
		Negative	Trace	1+	2+	3+	Total
Negative	Count	181					181
Trace	Count	13	23	2			38
1+	Count		3	30			33
2+	Count			4	11	3	18
3+	Count					19	19
Total	Count	194	26	36	11	22	289
	%Exact Match	93.3%	88.5%	83.3%	100.0%	86.4%	91.35%
	% +/- 1 Color block	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%

Glucose

Dip | U.S.		Predicate					
		Negative	Trace	1+	2+	3+	Total
Negative	Count	192					192
Trace	Count	10	25			1	36
1+	Count		7	6	1		14
2+	Count				9	7	16
3+	Count				4	27	31
Total	Count	202	32	6	14	35	289
	%Exact Match	95.0%	78.1%	100.0%	64.3%	77.1%	89.62%
	% +/- 1 color block	100.0%	100.0%	100.0%	100.0%	97.14%	99.65%

Usability:

Usability was evaluated in the 429 subjects who conducted the test for the first time – using native urine samples. 417 subjects (representing 97% of the total study participants) completed the test on their first try with no usability issues. Seven other subjects encountered challenges in using the device and performing the test within the designated 2-minute time frame. These subjects followed the Application Instructions and asked to re-do the test using a new kit. Each of these seven subjects successfully completed the test on their second try (increasing the number of subjects who were able to successfully complete the test to 424, representing a 99% usability success rate). Five subjects, representing 1% of the total study participants, failed to perform

the study and were unable to send out their test results. Subjects also filled out usability evaluations surveys to rank different aspects of the product's usability. 99% of the users reported that the it was easy or very easy (4 or 5 rating) to use the product.

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:

The patient does not receive test results from this test. The test results are sent to the prescriber. The following information about expected values is provided in the Physician Compendium which is available only to the prescriber.

Reference ranges:

Analyte	Expected Value
Glucose	Negative
Protein	Negative or trace
pH	4.6-8.0
Blood	Negative
Nitrite	Negative
Specific Gravity	1.001-1.035

Literature references are provided to support the stated reference ranges.

1. Brunzel, N.A. Fundamentals of Urine and Body Fluid Analysis. 2nd ed. Philadelphia:

Saunders. 2004.
2. Free, A. H., et al. Clinical Chemistry, 1957; 3: 716
3. Henry, J.B. et al. Clinical Diagnosis and Management of Laboratory Methods, 21st ed. Philadelphia: Saunders; 2007.
4. Tietz Fundamentals of Clinical Chemistry, 4th ed. Philadelphia: Saunders. 1996.

N. Instrument Name:

LG Nexus 5

O. System Descriptions:

1. Modes of Operation:

   Does the applicant's device contain the ability to transmit data to a computer, webserver, or mobile device?

   Yes ____X___ or No _____

   Does the applicant's device transmit data to a computer, webserver, or mobile device using wireless transmission?

   Yes ____X____ or No _____

2. Software:

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

   Yes ___X____ or No _____

3. Specimen Identification:

   The app will instruct the user to enter the patient ID using the keypad of the cell phone.

4. Specimen Sampling and Handling:

   The test is performed using midstream urine sample collected in a cup.

5. Calibration:

   Calibration is not needed.

6. Quality Control:

   The app has internal controls designed to account for environmental conditions that

impact the accuracy of the test.

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

1. The Color-Board and cup components were tested under various conditions (e.g., temperature, humidity) and shown to meet color and elasticity specifications for the Color-Board and cup, respectively. The study protocol and acceptance criteria were reviewed and found acceptable.

2. To assess potential carry-over a study was performed testing the effect of holding the test strips up and down for 15, 30, 60, 90 and 110 seconds, respectively, after dipping. The sponsor used positive and negative controls in the testing. Results of the negative control showed no carry-over. The results using the positive control indicated that after holding the stick in the up position for 30 seconds the pH measurements started to decrease. The instructions for use, both in the App and in the user manual, clearly describe the proper handling of the strip to prevent carry-over. The user is instructed to place the stick immediately on the Color-Board without delay.

3. To validate the recommended dipping time and to evaluate the impact of different dipping times on the test results, the sponsor conducted a study using negative and positive controls. None of the results were impacted by dipping times ranging from 1- to 5-seconds. The user is instructed to dip the strip in the urine for 1 second.

4. The sponsor conductedan assay time study in order to validate the recommended timeframe (from dipping to scanning the strip) and to evaluate the impact of different timeframes on the test results. The sponsor performed this study using negative and positive controls. Through the app-based flow, the user is instructed to scan the stick after 60 seconds have elapsed since dipping the stick. The sponsor tested time intervals at 60, 75, 90, and 110 seconds. None of the results were significantly impacted by the different timeframes evaluated.

5. Lighting study: The lighting study was done in a light chamber, simulating the five most popular types of light sources – GLS, Fluorescent, CFL, halogen and LED. The sponsor tested the effect of lighting using both the color sticks (five different printed stick configurations that covered 27 possible values on the reportable range) and urine samples (negative and positive urine samples), and tested them under 10 different lighting conditions that included: CFL6000K, CFL T2, CFL2700K, LED 2700K, LED 6000K, LED 6500K, Incandescent, Halogen, Fluorescent 2700K, Fluorescent 6000K. None of the results were impacted by the different lighting conditions evaluated.

6. Boundary study: The sponsor performed a study to demonstrate the environmental boundaries that would prevent accurate dipstick scanning by a lay user. If the distance is too far or too close, if the angle is too acute or obtuse, or the light is too dark, the DIP | U.S. algorithm will not permit the smartphone to capture an image. This study was performed using positive and negative urine samples and different printed sticks designed

to mimic test strips with different test results. At all boundary conditions evaluated, the test results were not significantly impacted.

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.