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

A. 510(k) Number:

k180356

B. Purpose for Submission:

New Device

C. Measurand:

Glucose, protein, leukocyte, nitrite and ketones in urine

D. Type of Test:

Qualitative and semi-quantitative urinalysis

E. Applicant:

Scanadu, Inc.

F. Proprietary and Established Names:

inui In-Home Urine Analysis Test System

G. Regulatory Information:

Name	Regulation	Product code	Device class
Urinary glucose (non-quantitative) test system	21 CFR 862.1340	JIL	II
Urinary protein or albumin (non-quantitative) test system	21 CFR 862.1645	JIR	I
Leukocyte peroxidase test	21 CFR 864.7675	LJX	I
Nitrite (non-quantitative) test system	21 CFR 862.1510	JMT	I
Ketones (non-quantitative) test system	21 CFR 862.1435	JIN	I

2. Panel:

Chemistry (75), Hematology (81)

H. Intended Use:

1. Intended use(s):

   See indications for use statement below.

2. Indication(s) for use:

   The inui In-Home Urine Analysis Test System consists of the inui In-Home Urine Analysis Device and the inui Urine Analysis Mobile Application. The inui In-Home Urine Analysis Test System is intended for detecting the following parameters in urine: protein, glucose, leukocytes, nitrites, and ketones. The test results provide information regarding the status of urinary tract infections (UTI), proteinuria, glucosuria, and ketonuria. These results can be used as an aid for monitoring kidney functions, metabolic disorders (e.g. diabetes mellitus), and can be used in the screening for urinary tract infections (UTI).

   The inui In-Home Urine Analysis Device is intended for use as a Prescription Home use device.

3. Special conditions for use statement(s):

   In vitro diagnostic use only.

   The inui In-Home Urine Analysis Test System is intended for prescription home use only. Not for visual read.

4. Special instrument requirements:

   iPhone 6 (iOS 8.X or higher)

I. Device Description:

The inui In-Home Urine Analysis Test System (inui Device) is comprised of a disposable test paddle, a urine collection cup, a gray background sheet, and the inui Urine Analysis Mobile Application. The plastic paddle contains multiple chemistry test pads (CTPs) and 1 quick response (QR) barcode. CTPs contain pre-dried chemicals that react to specific substances in a urine sample. A color reaction occurs on the CTP based on the amount of substance in the urine sample. The inui In-Home Urine Analysis Test System mobile app guides the user through the main steps of collecting urine, dipping the paddle into the urine, capturing an image of the reacted paddle, and displaying, saving, and sharing results.The inui In-Home Urine Analysis Device uses the mobile device's camera and the inui Urine Analysis Mobile Application to capture an image of the dipped CTPs, analyze the color changes and interpret the results. The results, are stored in Scanadu's secure encrypted cloud server for future reference. The inui In-Home Urine Analysis Test System must be used with a compatible mobile device (iPhone 6 with iOS version 8.X or higher). The inui Urine Analysis Mobile

Application installed on the mobile device serves as the only display for the inui Device. The list of compatible mobile devices is provided in the product labeling.

The inui In-Home Urine Analysis Device reports semiquantitative or qualitative values for each test parameter. The reportable ranges for each analyte are summarized below:

Analyte	Color block	Reportable range
Protein	1	Negative
	2	Trace (15 mg/dL)
	3	Moderate (30(+) mg/dL)
	4	Large (100(++)-2000(++++) mg/dL)
Glucose	1	Negative
	2	Low (100 mg/dL)
	3	Moderate-Large (250(+)-2000(++++) mg/dL)
Leukocyte	1	Negative-Trace
	2	Small-Large
Nitrite	1	Negative
	2	Positive
Ketone	1	Negative (0-5 mg/dL)
	2	Small (15 mg/dL)
	3	Moderate-Large (40-160 mg/dL)

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Siemens Multistix 10 SG Test Strips

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

   k992257

3. Comparison with predicate:

Similarities		
Item	Candidate Device Inui In-Home Analysis Device K180356	Predicate Device Mutistix 10 SG Test strips K992257
Intended Use	For the detection of protein, glucose, leukocytes, nitrites, and ketones	Same
Specimen	Urine	Same
Urine analyte detection methodology	Based on color change result from the reaction of urine analytes on test pads	Same

Differences		
Item	Candidate Device Inui In-Home Analysis Device K180356	Predicate Device Mutistix 10 SG Test strips K992257
Testing parameters	protein, glucose, leukocytes, nitrites, and ketones	leukocytes, protein, nitrites, blood, ketones, glucose, specific gravity, pH, bilirubin and urobilinogen
Special instrument requirements	Image capture by mobile phone's digital camera	Visual read by trained professionals or read on a Clinitek urinalysis instrument
Device Intended Users	Prescription home use by lay users	In near patient (point-of-care) and centralized laboratory locations.

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

- CLSI EP5-A3: Evaluation of Precision Performance of Quantitative Measurement Methods
- CLSI EP6-A: Evaluation of the Linearity of Quantitative Measurement Procedures
- CLSI EP7-A2: Interference Testing in Clinical Chemistry
- CLSI EP12-A2: User Protocol for Evaluation of Qualitative Test Performance
- CLSI EP17-A2: Evaluation of Detection Capability of Clinical Laboratory Measurement Procedures
- CLSI EP25-A: Evaluation of Stability of In Vitro Diagnostic Reagents

L. Test Principle:

The inui In-Home Urine Analysis Test System detects urine analytes based on colorimetry. A color reaction occurs on the chemical test pads, based on the concentration of chemicals present in the urine sample. The color reaction is captured as an image using the mobile device camera and read using the mobile application on the display screen of the mobile device. The results are reported as specified by the measurement range for each test.

Protein: This test is based on the protein error-of-indicator principle that produces a color change.

Glucose: This test is based on a double sequential enzyme reaction.

Leukocytes: This test is based on the action of esterase present in leukocytes, which catalyzes the hydrolysis of an indoxyl ester derivative. The indoxyl ester liberated reacts with a diazonium salt to produce a color change.

Nitrites: This test depends on the conversion of nitrate to nitrite by the action of Gram-negative bacteria in the urine.

Ketones: This test is based on the reaction of acetoacetic acid with sodium nitroprusside in a strongly basic medium to produce a color change.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Precision was evaluated with two studies; each study used three spiked urine solutions made from a pool of negative urine samples.

The first study determined the agreement between measurements using 3 phones and 3 paddle lot combinations with a single operator under one lighting condition with testing performed in one day. The study used 40 replicates resulting in N=120 per test level for the three controls solutions (P1 negative, P2 low positive and P3 high positive). Results for each control level for each analyte are summarized in the table below.

Analyte / Unit	Control solution	Target concentration	Expected results range	Exact agreement (%)	Agreement within ±1 block (%)
Glucose (mg/dL)	P1	0	Negative	100% (120/120)	100% (120/120)
	P2	95	Low (100 mg/dL)	100% (120/120)	100% (120/120)
	P3	1375	Moderate-Large (250-2000 mg/dL)	100% (120/120)	100% (120/120)
Ketone (mg/dL)	P1	0	Negative	100% (120/120)	100% (120/120)
	P2	0	Negative	100% (120/120)	100% (120/120)
	P3	75	Moderate-Large (40-160 mg/dL)	100% (120/120)	100% (120/120)
Protein (mg/dL)	P1	0	Negative	100% (120/120)	100% (120/120)
	P2	23	Trace (15 mg/dL)	100% (120/120)	100% (120/120)
	P3	250	Large (100 - 2000 mg/dL)	100% (120/120)	100% (120/120)
Nitrite (mg/dL)	P1	0	Negative	100% (120/120)	100% (120/120)
	P2	0	Negative	100% (120/120)	100% (120/120)
	P3	0.5	Positive	100% (120/120)	100% (120/120)
Leukocyte (U/mL)	P1	0	Negative	100% (120/120)	100% (120/120)
	P2	0	Negative	100% (120/120)	100% (120/120)
	P3	20	Small-Large	100% (120/120)	100% (120/120)

A second study was conducted across 3 phones, 3 paddle lots, under 2 lighting conditions (incandescent (INC) and compact fluorescent (CFL) which the sponsor stated were the most common lighting conditions), using 2 replicates, 3 solutions and 3 users for 5 non-consecutive days resulting in N=180 tests per sample. Results for each control level for each analyte are summarized in the table below.

Analyte / Unit	Control solution	Target concentration	Expected test results	Exact agreement (%)	Agreement within ±1 block (%)
Glucose (mg/dL)	P1	0	Negative	100% (180/180)	100% (180/180)
	P2	95	Low (100 mg/dL)	100% (180/120)	100% (180/180)
	P3	1375	Moderate-Large (250-2000 mg/dL)	100% (180/180)	100% (180/180)
Ketone (mg/dL)	P1	0	Negative-Trace	100% (180/180)	100% (180/180)
	P2	0	Small (15 mg/dL)	100% (180/180)	100% (180/180)
	P3	75	Moderate-Large (40-160 mg/dL)	100% (180/180)	100% (180/180)
Protein (mg/dL)	P1	0	Negative	100% (180/180)	100% (180/180)
	P2	23	Trace (15 mg/dL	100% (180/180)	100% (180/180)
	P3	250	Moderate-Large (100-2000 mg/dL)	100% (180/180)	100% (180/180)
Nitrite (mg/dL)	P1	0	Negative	100% (180/180)	100% (180/180)
	P2	0	Negative	100% (180/180)	100% (180/180)
	P3	0.5	Positive	100% (180/180)	100% (180/180)
Leukocyte (U/mL)	P1	0	Negative-Trace	100% (180/180)	100% (180/180)
	P2	0	Negative-Trace	100% (180/180)	100% (180/180)
	P3	20	Small-Large	100% (180/180)	100% (180/180)

b. Linearity/assay reportable range:

Five different lighting conditions representing incandescent (INC), compact fluorescent (CFL), LED, daylight (D65) and halogen (HAL) were used to determine the linearity and limit of detection for each analyte. Measurements were made using three phones, three paddle lots, three operators, and three replicates = N of 45 for each solution. Some solutions had less than 45 replicates because no test result was generated or the samples were depleted. Contrived samples were generated using a negative fresh urine sample spiked with commercially available reagents to obtain the target range of concentrations. For each analyte, the cutoff levels were defined as concentrations where at least 50% of results belonged to the next corresponding level. The results are provided in the tables below:

Analyte	Conc. (U/mL)	Negative-Trace	Small-Large
Leukocyte	0	100% (45/45)	
	0.0014	97.8% (44/45)	2.2% (1/45)
	0.0016	95.6% (43/45)	4.4% (2/45)
	0.0018	77.8% (35/45)	22.2% (10/45)
	0.0019	80% 36/45)	20% (9/45)
	0.002	68.9% (31/45)	31.1% (14/45)
	0.0023	31.1% (14/45)	68.9% (31/45)
	0.0038	4.40% (2/45)	95.6% (43/45)

Analyte	Conc. (U/mL)	Negative-Trace	Small-Large
	0.0075		100% (45/45)
	0.16		100% (45/45)

Analyte	Conc. (mg/dL)	Negative-Trace	Small-Large
Nitrite	0	100% (45/45)	
	0.0025	100% (45/45)	
	0.025	14% (6/44)	86% (38/44)
	0.05		100% (45/45)
	0.1		100% (43/43)
	0.125		100% (43/43)
	0.2		100% (41/41)
	0.25		100% (46/46)
	0.3	2 (1/45)	98% (44/45)

Analyte	Conc. (mg/dL)	Negative	Trace (15 mg/dL)	Moderate (30 mg/dL)	Large (100 – 2000 mg/dL)
Protein	0	100% (45/45)			
	5	100% (45/45)			
	9	80% (36/45)	20% (9/45)		
	10	46.7% (21/45)	53.3% (24/45)		
	11	20% (9/45)	80% (36/45)		
	13	2.2% (1/45)	97.8% (44/45)		
	21		73.3% (33/45)	26.7% (12/45)	
	23		33.3% (15/45)	66.7% (30/45)	
	26		6.7% (3/45)	93.3% (42/45)	
	30		2.2% (1/45)	97.8% (44/45)	
	50			91.1% (41/45)	8.9% (4/45)
	60			44.4% (20/45)	55.6% (25/45)
	77			8.9% (4/45)	91.1% (41/45)
	86			4.4% (2/45)	95.6% (43/45)
	100				100% (45/45/45)
	300				100% (45/45/45)
	750				100% (45/45/45)
	1500				100% (45/45/45)
	2000				100% (45/45/45/45)

Analyte	Conc. mg/dL	Negative	Low (100 mg/dL)	Moderate – Large (250-2000 mg/dL)
Glucose	0	100% (45/45)		
	15	100% (45/45)		
	25	100% (9/9)		
	50	2.33% (1/43)	97.67% (45/45)	
	75		100% (45/45)	
	105		100% (44/44)	
	137.5		97.73% (43/45)	2.27% (1/45)
	175		54.55% (24/45)	45% (20/45)
	212.5		2.33% (1/45)	97.67% (42/45)
	250			100% (44/44)
	505			100% (29/29)
	1000			100% (29/29)
	2200			100% (29/29)
	2300			100% (30/30)

Analyte	Conc. mg/dL	Negative-Trace 0-5 mg/dL)	Small (15 mg/dL)	Moderate-Large (40-160 mg/dL)
Ketone	0	100% (45/45)		
	2	100% (45/45)		
	8	73% (32/45)	27% (12/44)	
	10	9% (4/45)	91% (40/44)	
	13		100% (45/45)	
	15		100% (45/45)	
	21		89% (32/36)	11% (4/36)
	28		17% (6/35)	83% (29/35)
	34		3% (1/35)	97% (34/35)
	40			100% (35/35)

Based on these results, the sponsor defined the following cutoffs for each analyte level (color block).

Analyte	**Level 1**	**Level 2**	**Level 3**	**Level 4**
Protein	< 10 mg/dL	>10 mg/dL and <23 mg/dL	>23 mg/dL and <60 mg/dL	>60 mg/dL
Glucose	< 50 mg/dL	50 mg/dL and 175 mg/dL	above 175 mg/dL	NA
Leukocyte	< 0.0023 U/mL	> 0.0023 U/mL and above	NA	NA
Nitrite	< 0.025 mg/dL	0.025 mg/dL and above	NA	NA
Ketone	< 10 mg/dL	10 mg/dL and <28 mg/dL	28 mg/dL and above	NA

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

The device is not traceable to a standard or method.

d. Detection limit:

See Section M.1.b. for evaluation of the detection limit.

e. Analytical specificity:

Three solutions were used for interference study prepared from a natural pool of negative urine samples obtained from urine donors. The solution "Neg Ctrl" is a pooled human negative urine for all analytes. The solution "Pos 1" is low positive urine for Leukocyte (2 U/mL), Nitrite (0.1 mg/L), and Glucose (260 mg/dL) concentrations. The solution "Pos 2" is a low to moderate positive urine solution for Protein (100 mg/dL) and Ketone (40 mg/dL) concentrations.

To determine whether a substance is potentially interfering, high concentration of the substance was spiked in the positive (Pos 1 and Pos 2) and negative controls (Neg Ctl). A substance is considered an interferent if there was a result ± 1 level from the expected result/control. Concentrations of the potentially interfering substances that did not produce a change in both the negative and positive pools are shown in the table below:

Interfering Substance	**Concentration Tested (mg/dL)**
Creatine	10
Fructose	18
Ammonium Chloride	200
Ascorbic Acid	2.2
Amoxicillin	7.5
Citric Acid	6
Creatinine	500
Galactose	15.13
Glycine	450
Oxalic Acid	0.73
Sodium Acetate	1200
Cephalexin	11.7
Calcium Chloride	300
Ciprofloxacin	1
Sodium Chloride	648
Potassium Chloride	37
Sodium Nitrate	0.3
Sodium Phosphate	25.2

Interfering Substance	Concentration Tested (mg/dL)
Urea	120
Acetaminophen	20
Phenolphthalein	986
Theophylline	10
Lactose	226

The following interferences were observed and are described in the instructions for use labeling:

Urine Analyte	Positive Bias / Increase in results	Negative bias / Decrease in results
Protein	Albumin (Expected Interferent)	Acetoacetic Acid (invalid results at all conc)*
	Bilirubin (>10 mg/dL)	
	Hemoglobin (>100 mg/dL)	Hypochlorite (>375 mg/dL)
	Chlorhexidine (>40 mg/dL)	Specific Gravity (>1.025)
	Riboflavin (>5 mg/dL)	
Leukocyte	Leukocyte (Expected Interferent)	Acetoacetic Acid (invalid results at all conc)*
		Albumin (>3000 mg/dL)
		Bilirubin (>10 mg/dL)
	Hemoglobin (>150 mg/dL)	Sodium Chloride (>324 mg/dL)
		Hemoglobin (>100 mg/dL)
		Hypochlorite >(375 mg/dL)
		Chlorhexidine (>60 mg/dL)
		Microbial Peroxidase (>0.65%)
		Riboflavin (>5 mg/dL)
		Sodium Acetate (>600 mg/dL)
		Sodium Bicarbonate (>630 mg/dL)
		Specific gravity (>1.020)
		Urobilinogen (>4 mg/dL)
Nitrite	Sodium Nitrite (Expected Interferrent)	Hypochlorite (>375 mg/dL)
	Hemoglobin (>100 mg/dL)	
	Hypochlorite (>375 mg/dL)	
	Leukocyte (>0.0375 U/mL)	Sodium Bicarbonate (>945mg/dl)
	Urobilinogen (>4 mg/dl)	Sodium Acetate (>900 mg/dL)
Ketone	Litihium Acetoacetate (Expected Interferent)	Hypochlorite (>375 mg/dL)
		Sodium Nitrite (>7.5 mg/dL)
Glucose	D-(+)-Glucose (Expected Interferent)	Acetoacetic Acid (invalid results at all conc)*
	Hypochlorite (>375 mg/dL)	Lithium Acetoacetate (>80 mg/dL)
	Bilirubin (Invalid results at all conc)*	Sodium Chloride (>486 mg/dL)

* These interferents produce results that are outside the expected color trajectory. The inui App detects these interferents and reports the result as invalid.

f. Assay cut-off:

Not Applicable.

2. Comparison studies:

a. Method comparison with predicate device:

Two method comparison studies were performed. Method comparison study 1 was performed to evaluated glucose, nitrite and ketones and method comparison study 2 was performed to evaluated protein and leukocytes. Both studies were conducted using subjects at two clinical sites. The agreement with the predicate device was evaluated with results obtained by lay users testing the inui Device (proposed device) with urine samples compared with results generated using the Siemens Multistix 10SG (predicate device) test strips tested and visually read by professional users. De-identified urine samples were collected from various geographic locations in the US. 338 samples were tested for method comparison study-1 and 177samples were tested for method comparison study-2 (<3.0% of the total samples were contrived). Subjects were asked to test two clinical samples, their own urine sample and one provided to them from the collected pool of de-identified urine samples. The urine samples were randomized and blinded to both the lay users and professionals testing the samples. To adequately cover the positive ranges across all analyte levels, contrived specimens were included in the study. The data from each site was combined and are presented in the tables below showing the percent exact agreement and the percent agreement within ±1 color block.

Glucose		Predicate Device (Professionals)						Total Samples Used
		NEG	Low (100mg/dL)	250 mg/dL	550 mg/dL	1000 mg/dL	2000 mg/dL	
Proposed Device (Layuser)	NEG	278	2	0	0	0	0	338
	Low (100)	0	14	0	0	0	0	
	250/500/1000 /2000	0	3	7	6	9	19	
Total		278	19	7	6	9	19	
% exact match		100%	73.68	100%				
% ±1 color block		100%	100%	100%				

Nitrite		Predicate Device			Total Samples Used
		NEG	Low Positive	High Positive	
Proposed Device	NEG	282	0	0	338
	Positive	11	15	30	
Total		293	15	30	
% exact match		96.25%	100%		
% ±1 color block		100%	100%		

Ketone		Predicate Device						Total Samples Used
		NEG	Trace	Small	Moderate	Large	Large	
Proposed Device	NEG/Trace	286	14	0	0	0	0	338
	Small	0	4	12	0	0	0	
	Moderate(40)/Large (80)/Large (160)	0	0	6	9	3	4	
Total		286	18	18	9	3	4	
% exact match		98.68%		66.67%	100%			
% ±1 color block		100%	100%	100%	100%			

Protein		Predicate Device						Total Samples Used
		NEG	Trace	30 mg/dL	100 mg/dL	300 mg/dL	2000 mg/dL	
Propose Device	NEG	92	5	0	0	0	0	177
	Trace-Small (30mg/dL)	19	27	0	0	0	0	
	Moderate (30 mg/dL)	0	4	9	0	0	0	
	Large (100 –2000 mg/dL)	0	0	1	10	5	5	
Total		111	36	10	10	5	5	
% exact match		83%	75%	90%	100%			
% ±1 color block		100%	100%	100%	100%			

Leukocytes		Predicate Device					Total Samples Used
		NEG	Trace	Small	Moderate	Large	
Propose Device	NEG/Trace	82	26	2	0	0	177
	Small/Mod/Large	0	0	24	25	18	
Total		82	26	26	25	18	
% exact match		100%	100%	92.3%	100%	100%	
% ±1 color block		100%	100%	100%	100%	100%	

b. Matrix comparison:

Not Applicable.

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):

Usability and human factors testing was performed to evaluate the ability of the lay users to perform urine testing with the inui In-Home Urine Analysis System under the intended use conditions with the package insert. The study evaluated the overall process flow in the hands of the lay users, the impact of critical device components (i.e. packaging, urine collection cup, CTP test paddle and inui App) and user satisfaction. Usability testing resulted in acceptable performance for all critical actions in the testing procedure confirming that the lay users can follow the entire procedural steps (from sign-in and, test set-up to understanding the results) to obtain a successful test result.

4. Clinical cut-off:

Not Applicable.

5. Expected values/Reference range:

Analyte	Results	Recommendations (Call to Action)
Protein	Negative	Your test result is normal. Note: Consult your physician if symptoms of any medical conditions are present.
	Trace (15 mg/dL)	Consult your physician if protein is consistently present or increasing in your urine.
	Moderate (30(+) mg/dL)	Consult your physician.
	Large (100(++) – 2000 (++++) mg/dL)	Consult your physician immediately.
Glucose	Negative	Your test result is normal. Note: Consult your physician if symptoms of any medical conditions are present.
	Low (100 mg/dL)	Consult your physician if glucose is consistently present or increasing.
	Moderate-Large (250(+) – 2000 (++++) mg/dL)	Consult your physician immediately.
Leukocyte	Negative-Trace	Your test result is normal. Note: Consult your physician if symptoms of any medical conditions are present.
	Small(+) – Large (+++)	Consult your physician.
Nitrite	Negative	Your test result is normal. Note: Consult your physician if symptoms of any medical conditions are present.
	Positive	Consult your physician immediately
Ketone	Negative-Trace	Your test result is normal. Note: Consult your physician if symptoms of any medical conditions are present.
	Small (15 mg/dL)	Consult your physician.
	Moderate-Large (40-160 mg/dL)	Consult your physician immediately

N. Instrument Name:

iPhone 6 (iOS 8.X or higher)

O. System Descriptions:

1. Modes of Operation:

   Smartphone image capture and analysis of the chemical test pad (CTP) colors to determine the analyte concentration.

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:

   There is no sample identification function with these devices. Samples are applied directly to the urinalysis strips as they are collected.

4. Specimen Sampling and Handling:

   The device is intended to be used with a freshly collected urine sample. The App instructs the user to image the test strip (to obtain a test result) no more than two minutes after sample application.

5. Calibration:

   The inui In-Home Urine Analysis Device paddle is affixed with a quick response code (QR). The QR code is a unique ID that will contain information including the paddle expiration and lot number. The QR code has a built-in quality control system to reject the paddle if it has been used previously on the same phone.

6. Quality Control:

   The reference color bar (RCB) on the label serves as an internal control for color correction of each captured image to account for the different ambient conditions.

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

Studies were performed to validate insensitivity of the inui In-Home Analysis Test System to varying environmental and user conditions.

1. Lighting effect: The performance of the device in different lighting conditions and illuminance was evaluated. The sponsor concluded having the phone flashlight or torch light on allows the app algorithm to remove light variability. The labeling indicates that testing should be conducted under normal household lighting conditions (i.e. incandescent, CFL, LED or halogen). The App warns the user if there is improper lighting conditions or the lighting conditions are not optimal.

2. Height and Angle study: image capture height, angle and alignment was evaluated to determine optimum range to capture the CTP paddle image. The optimal height and angle is incorporated in the app to give real time feedback to the user holding the phone. The App detects the height and angle of the strip or if the strip is misaligned and will warn the user with real time feedback.

3. Battery Life and Torch Light Intensity study: The sponsor evaluated whether the flashlight or torch light intensity correlates with the battery life and the phones ability to capture the CTP test paddle image. The study concluded that torch light intensity is not dependent on battery life.

4. Paddle Air Exposure study: The effect of air exposure on the chemical test pads on the paddle was evaluated. The study concluded the prolonged exposure (>15 minutes) to air can reduce activity of the CTP. The package insert states under "Precautions": Conducting the test is very time sensitive. Please read all directions and follow all steps as instructed. Do NOT open pouch until instructed to by the app.

5. Paddle Dip time study: The paddle dip time was evaluated at 1, 3, 7 and 10 seconds using 3 contrived urine solutions. There were 10 replicates for each of the 5 dip times. No differences were observed between dip times and the analyte concentrations reported. The package insert recommends under "Precautions": Do not dip paddle in urine for more than 1 second.

6. Single or Double Dip study: This study evaluated the effect of double dipping a paddle into a urine sample. A double dip consisted of submerging the test paddles into contrived urine solutions for one second, removing the paddles from the solution for another second and finally submerging the paddles into the solution for a second time for an additional second. The timer on the app was then initiated after the second submersion was completed. No changes were observed between single dipping and double dipping of paddles in regards to app results however the recommendation in the package insert states: Do not use test paddle more than once.

7. Urine Temperature Variation study: The effect of urine temperature variation on analytes was evaluated. Samples were tested at both 25°C and 35°C. Under both temperature conditions (25 °C and 35 °C) all 5 analytes tested 100% concordance with the expected results.

Q. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Parts 801 and 809, as applicable.

R. Conclusion:

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