510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE

A. 510(k) Number:
k061559

B. Purpose for Submission:
Clearance of a new device

C. Measurand:
Urinary Glucose, Occult Blood, Leukocytes, pH, Nitrite, Protein, Ketones, Urobilinogen, Bilirubin, Specific Gravity and Ascorbic Acid

D. Type of Test:
Qualitative and semi-quantitative urine tests

E. Applicant:
ACON Laboratories, Inc.

F. Proprietary and Established Names:
ACON Urinalysis Reagent Strips

G. Regulatory Information:

1. Regulation section:
   21 CFR § 862.1340 Urinary Glucose (Non-Quantitative) Test System
   21 CFR § 862.1115 Urinary Bilirubin and its Conjugates (Non-Quantitative) Test System
   21 CFR § 862.1435 Ketones (Non-Quantitative) Test System
   21 CFR § 864.6550 Occult Blood Test
   21 CFR § 862.1550 Urinary pH (Non-Quantitative) Test System
   21 CFR § 862.1645 Urinary Protein or Albumin (Non-Quantitative) Test System
   21 CFR § 862.1785 Urinary Urobilinogen (Non-Quantitative) Test System
   21 CFR § 862.1510 Nitrite (Non-Quantitative) Test System
   21 CFR § 864.7675 Leukocyte Peroxidase Test
   21 CFR § 862.1095 Ascorbic Acid Test System

2. Classification:
   Class II: Urinary Glucose and Occult Blood

   Class I: Urinary Leukocytes, Urinary pH, Nitrite, Urinary Protein, Ketones, Urinary Urobilinogen, Urinary Bilirubin, Specific Gravity and Ascorbic Acid

3. Product code:
   JIL Urinary Glucose (non-quant.) test system
   JIO Blood, Occult, Colorimetric, in urine

LJX Test, Urine Leukocyte
CEN Urinary, pH (non-quant.)
JMT Nitrite (urinary, non-quant.) test system
JIR Protein or Albumin (urinary, non-quant.) test system
JIN Ketones (urinary, non-quant.) test system
CDM Urinary Urobilinogen (non-quant.) test system
JJB Urinary Bilirubin & its conjugates (urinary, non-quant.) test system
JMA Acid, Ascorbic, 2, 4-Dinitrophenylhydrazine (Spectrophotometric)

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

H. Intended Use:

1. Intended use(s):
The ACON Urinalysis Reagent Strips are for the qualitative and semi-quantitative detection of one or more of the following analytes in urine: glucose, bilirubin, ketone (acetoacetic acid), specific gravity, blood, pH, protein, urobilinogen, nitrite, leukocytes and ascorbic acid. It is intended for professional use only.

2. Indication(s) for use:
The ACON Urinalysis Reagent Strips (Urine) are for the qualitative and semi-quantitative for detection of one or more of the following analytes in urine: Glucose, Bilirubin, Ketone (Acetoacetic acid), Specific Gravity, Blood, pH, Protein, Urobilinogen, Nitrite, Leukocytes and Ascorbic Acid.

The ACON Urinalysis Reagent Strips (Urine) are for single use in professional near-patient (point-of-care) and centralized laboratory locations. The strips are intended for use in screening at-risk patients to assist diagnosis in the following areas:

- Kidney function
- Urinary track infections
- Carbohydrate metabolism (e.g. diabetes mellitus)
- Liver function
- Acid-base balance
- Urine concentration

The results can be used along with other diagnostic information to rule out certain disease states and to determine if microscopic analysis is needed. The test is to be read visually. It is intended for professional use only.

3. Special conditions for use statement(s):
For prescription use

4. Special instrument requirements:

Not applicable. The device is a visually read single-use device.

I. Device Description:

The ACON Urinalysis Reagent Strips are urine test strips of which glucose, bilirubin, ketone, specific gravity, blood, pH, protein, urobilinogen, nitrite and leukocyte reagent pads are affixed onto the plastic strips. The reagent pads react with the urine and provide a visible color reaction. Results are obtained by direct comparison of the test strip with the color blocks printed on the bottle label. The product is packaged with a drying agent in a plastic bottle. The entire reagent strip is disposable when the disposal directions are followed exactly. Laboratory instrumentation is not required. These tests are intended for professional use with human urine.

J. Substantial Equivalence Information:

1. Predicate device name(s):
   Bayer Multistix 10 SG Reagent Strips for Urinalysis

2. Predicate 510(k) number(s):
   k905396

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended Use	Professional use in point-of-care urine testing	Same
Target Population	Patients of physicians, hospitals, and clinics	Same
Intended Specimen	Urine	Same
Material Provided	Plastic strips affixed with several separate reagent areas.	Same
Visual read test time	Varies from 30 Seconds to 2 Minutes	Same
Glucose Methodology	Same	Same
Bilirubin Methodology	Same	Same
Ketone Methodology	Same	Same
Specific Gravity Methodology	Same	Same
Blood Methodology	Same	Same
pH Methodology	Same	Same
Protein Methodology	Same	Same
Urobilinogen Methodology	Same	Same
Nitrite Methodology	Same	Same
Leukocyte Methodology	Same	Same

Differences		
Item	Device	Predicate
Ascorbic Acid Methodology	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.	This test is not included on Bayer test strip.
Storage	2 to 30ºC	15 to 30ºC

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

None were identified by the applicant.

L. Test Principle:

Glucose: This test is based on the enzymatic reaction that occurs between glucose oxidase, peroxidase and chromogen. Glucose if 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. Low amounts of glucose are normally excreted in urine. Glucose concentrations as low as 100 mg/dL, read at either 10 or 30 seconds, may be considered abnormal if results are consistent. At 10 seconds, results should be interpreted qualitatively. For semi-quantitative results, read at 30 seconds only.

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. In normal urine, no bilirubin is detectable by even the most sensitive methods. Even trace amounts of bilirubin require further investigation. Atypical results (colors different from the negative or positive color blocks shown on the color chart) may indicate that bilirubin-derived bile pigments are present in the urine specimen, and are possibly masking the bilirubin reaction.

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. Ketones are normally not present in urine. Detectable ketone levels may occur in urine during physiological stress conditions such as fasting, pregnancy and frequent strenuous exercise. In starvation diets, or in other abnormal carbohydrate metabolism situations, ketones appear in the urine in excessively high concentration before serum ketones are elevated.

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. Randomly collected urine may vary in specific gravity from 1.003-1.035. Twenty-four hour urine from healthy adults with normal diets and fluid intake will have a specific gravity of 1.016-1.022. In cases of severe renal damage, the specific gravity is fixed at 1.010, the value of the glomerular filtrate.

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. Any green spots or green color development on the reagent area within 60 seconds is significant and the urine specimen should be examined further. Blood is often, but not invariably, found in the urine of menstruating females.

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. The expected range for normal urine specimens from newborns is pH 5-7. The expected range for other normal urine specimens is pH 4.5-8, with an average result of pH 6.

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. 1-14 mg/dL of protein may be excreted by a normal kidney. A color matching any block greater than trace indicates significant proteinuria.

Urobilinogen: This test is based on a modified Ehrlich reaction between p-diethylaminobenzaldehyde and urobilinogen acid in strongly acidic medium to produce a pink color. Urobilinogen is one of the major compounds produced in heme this test is 0.2-1.0 mg/dL (3.5-17 μmol/L). A result of 2.0 mg/dL (35 μmol/L) may be of clinical significance, and the patient specimen should be further evaluated.

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 1 N-(1-naphthyl)-ethylenediamine to produce a pink color. Nitrite is not detectable in normal urine. The nitrite area will be positive in some cases of infection, depending on how long the urine specimens were retained in the bladder prior to collection. Retrieval of positive cases with the nitrite test ranges from as low as 40% in cases where little bladder incubation occurred, to as high as approximately 80% in cases where bladder incubation took place for at least 4 hours.

Leukocytes: This test reveals the presence of granulocyte esterases. The esterases cleave a derivatized pyrazole amino acid ester to liberate derivatized hydroxy

pyrazole. This pyrazole then reacts with a diazonium salt to produce a beige-pink to purple color. Normal urine specimens generally yield negative results. Trace results may be of questionable clinical significance. When trace results occur, it is recommended to retest using a fresh specimen from the same patient. Repeated trace and positive results are of clinical significance.

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.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:
   a. *Precision/Reproducibility:*
   This reproducibility study employed two Bio-Rad Urinalysis Controls: Bio-Rad Urinalysis Control Level 1 and Bio-Rad Urinalysis Control Level 2. The specifications of these two controls are listed in the following tables.

Bio-Rad Urinalysis Control, Level 1 values

Analyte	Control (Level 1)
Glucose	Neg
Bilirubin	Neg
Ketone	Neg
Specific Gravity	1.010 – 1.020
Blood	Neg
pH	5.0 – 6.0
Protein	Neg
Urobilinogen	0.2 – 1.0 mg/dL
Nitrite	Neg
Leukocytes	Neg
Ascorbic Acid	Neg

Bio-Rad Urinalysis Control, Level 2 values

Analyte	Control (Level 2)
Glucose	250 - ≥ 1,000 mg/dL
Bilirubin	Mod. - Large
Ketone	5 – 40 mg/dL
Specific Gravity	1.015 – 1.025
Blood	Mod. - Large
pH	6.5 – 7.5
Protein	30 - ≥ 300 mg/dL
Urobilinogen	4.0 - 8.0 mg/dL
Nitrite	Positive
Leukocytes	Small – Large
Ascorbic Acid	Neg

Three lots of the ACON Urinalysis Reagent Strips were used. Tests in duplicates were performed with 10 repeats by 5 operators per day for 10 days. A total of 3,000 strips were used for testing (3 x 2 x 10 x 5 x 10 = 3,000 strips). Results were read by comparing color reaction to the color blocks on the canister label according to the instructions on the package insert. The results indicate that the values obtained were all within the expected values for the control materials.

As the urinalysis controls did not have an ascorbic acid level, the sponsor used two ascorbic acid standard positive solutions, 10 mg/dL and 20 mg/dL. Testing was performed according to the package insert and the results were determined by visually comparing the reaction colors with the color chart. The ACON Urinalysis Reagent Strips from 3 lots were used and tests were performed in replicates of 10 for 2 runs by 10 operators per day for 10 days. The results indicate that the values obtained were all within the expected values for the control materials.

b. Linearity/assay reportable range:

Reagent	Range
Glucose (GLU)	50-100 mg/dL (2.5-5 mmol/L). Results may be read at 10 seconds for qualitative results or at 30 seconds for semi-quantitative results.
Bilirubin (BIL)	0.4-1.0 mg/dL (6.8-17 µmol/L).
Ketone (KET)	2.5-5 mg/dL (0.25-0.5 mmol/L).
Specific Gravity (SG)	Range: 1.000-1.030
Blood (BLO)	0.018-0.06 mg/dL or 5-10 Ery/µL in urine specimens with ascorbic acid content of <50 mg/dL.
pH	Range: 5.0-9.0
Protein (PRO)	7.5-15 mg/dL (0.075-0.15 g/L).
Urobilinogen (URO)	0.2-1.0 mg/dL (3.5-17 µmol/L).
Nitrite (NIT)	0.05-0.1 mg/dL in urine with a low specific gravity and less than 30 mg/dL ascorbic acid.
Leukocytes (LEU)	9-15 white blood cells Leu/µL in clinical urine.
Ascorbic Acid (ASC)	5-10 mg/dL (0.28-0.56 mmol/L).

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

The sponsor did not indicate any degree of traceability for their devices. Control materials are not specifically identified in the labeling, but the sponsor indicates in the labeling that for best results, performance of reagent strips should be confirmed by testing known positive and negative specimens/controls whenever a new test is performed, or whenever a new canister is first opened.

The recommended storage temperature range for the ACON Urinalysis Reagent Strips is between 2 – 30°C. Opened canister stability claim of the strips is that the strips are stable for at least 3 months. Unopened canister stability claim of the strips is that the strips are stable for 24 months from the date of manufacture.

d. *Detection limit:*

The sensitivity of the assay was validated by spiking positive urine samples of known concentrations for each analyte. These positive samples of each analyte were then diluted to the lowest "positive" concentrations indicated on the ACON color chart. For each analyte, aliquots of the lowest positive samples were further diluted to 4:1 or 80%, 3:2 or 60%, 1:1 or 50% and 1:3 or 25% of the originals with negative urine. Urine samples including negative and all spiked and diluted samples were then tested with three lots of the ACON Urinalysis Reagent Strips. For three consecutive days, each sample was tested 21 times by three operators (7 strips per operator per day). A total of 189 strips were used for each concentration tested (3 operators x 3 days x 7 strips x 3 lots = 189 strips). The minimum sensitivity level for each analyte of the ACON Urinalysis Reagent Strips is defined by the sponsor as the lowest level at which over 67% (2/3) of the test results are positive when the diluted positive samples for an analyte of known concentrations were tested. The results of each analyte sensitivity pad are summarized below. Gray blocks identify the low range (sensitivity) of each analyte.

Glucose Pad -

Results						
Glucose Conc.	**N**	**Neg.**	**100 mg/dL***	**250 mg/dL**	**500 mg/dL**	**% Positive**
25 mg/dL	189	189	0	0	0	0.0%
50 mg/dL	189	63	125	0	0	67.2%
60 mg/dL	189	0	189	0	0	100.0%
80 mg/dL	189	0	189	0	0	100.0%
100 mg/dL	189	0	189	0	0	100.0%

* Lowest Positive Concentration

Bilirubin Pad -

Results						
Bilirubin Conc.	**N**	**Neg.**	**1 mg/dL***	**2 mg/dL**	**4 mg/dL**	**% Positive**
0.25 mg/dL	189	189	0	0	0	0.0%
0.4 mg/dL	189	62	127	0	0	67.2%
0.6 mg/dL	189	62	127	0	0	67.2%
0.8 mg/dL	189	0	189	0	0	100.0%
1.0 mg/dL	189	0	189	0	0	100.0%

* Lowest Positive Concentration

Ketone Pad -

Results							
Ketone Conc.	**n**	**Neg.**	**5 mg/dL***	**15 mg/dL**	**40 mg/dL**	**80 mg/dL**	**% Positive**
1.25 mg/dL	189	189	0	0	0	0	0.0%
2.5 mg/dL	189	63	126	0	0	0	67.2%
3 mg/dL	189	0	189	0	0	0	100.0%
4 mg/dL	189	0	189	0	0	0	100.0%
5 mg/dL	189	0	189	0	0	0	100.0%

* Lowest Positive Concentration

Blood Pad -

Results					
Blood Conc.	**n**	**Neg.**	**5-10 Ery/µL***	**50 Ery/µL**	**% Positive**
2.5 Ery/µL	189	94	95	0	50.0%
5 Ery/µL	189	0	189	0	100%
6 Ery/µL	189	0	189	0	100%
8 Ery/µL	189	0	189	0	100%
10 Ery/µL	189	0	189	0	100%

* Lowest Positive Concentration

Results					
Hemoglobin Conc.	**n**	**Neg.**	**+/- Color Block**	**+ Positive Block**	**% Positive**
0.0075 mg/dL	189	189	0	0	0.0%
0.015 mg/dL	189	127	62	0	33.3%
0.018 mg/dL	189	62	127	0	66.7%
0.024 mg/dL	189	0	189	0	100%
0.03 mg/dL	189	0	189	0	100%
0.06 mg/dL	189	0	0	189	100%

Protein Pad -

Results						
Protein Conc.	**n**	**Neg.**	**15 mg/dL***	**30 mg/dL**	**100 mg/dL**	**% Positive**
3.75 mg/dL	189	189	0	0	0	0.0%
7.5 mg/dL	189	63	126	0	0	67.2%
9.0 mg/dL	189	9	180	0	0	95.2%
12.0 mg/dL	189	0	189	0	0	100.0%
15.0 mg/dL	189	0	189	0	0	100%

* Lowest Positive Concentration

Urobilinogen Pad -

Results						
Urobilinogen Conc.	**n**	**0.2 mg/dL**	**1.0 mg/dL**	**2 mg/dL**	**4 mg/dL**	**% Agreement**
0.2 mg/dL	189	189	0	0	0	100.0% (first color block)
0.25 mg/dL	189	189	0	0	0	100.0% (first color block)
0.5 mg/dL	189	189	0	0	0	100.0% (first color block)
0.6 mg/dL	189	105	84	0	0	44.4% (second color block)
0.8 mg/dL	189	0	189	0	0	100.0% (second color block)
1.0 mg/dL	189	0	189	0	0	100.0% (second color block)

Urine urobilinogen concentration above 1 mg/dL is considered "Abnormal". The minimum sensitivity level of urobilinogen was selected at 0.2 mg/dL. The test is not a reliable method for the detection of Porphobilinogen. The absence of Urobilinogen cannot be detected by the test.

Nitrite Pad -

Results				
Nitrite Conc.	**n**	**Neg.**	**Pos.**	**% Positive**
0.025 mg/dL	189	189	0	0.0%
0.05 mg/dL	189	5	184	97.4%
0.06 mg/dL	189	0	189	100%
0.08 mg/dL	189	0	189	100%
0.1 mg/dL	189	0	189	100%

Leukocytes Pad -

Results (Cells/µL)						
Leukocytes Conc.	**n**	**Neg.**	**15***	**70**	**125**	**% Positive**
3.75 Cells/µL	189	189	0	0	0	0.0%
7.5 Cells/µL	189	130	59	0	0	31.2%
9 Cells/µL	189	63	126	0	0	67.2%
10 Cells/µL	189	0	189	0	0	100.0%
12 Cells/µL	189	0	189	0	0	100.0%
15 Cells/µL	189	0	189	0	0	100.0%

* Lowest Positive Concentration

Ascorbic Acid Pad -

Results (mg/dL)						
Ascorbic Acid Conc.	**n**	**Neg.**	**10***	**20**	**40**	**% Positive**
2.5 mg/dL	189	189	0	0	0	0.0%
5 mg/dL	189	0	189	0	0	100%
6 mg/dL	189	0	189	0	0	100%
8 mg/dL	189	0	189	0	0	100%
10 mg/dL	189	0	189	0	0	100%

* Lowest Positive Concentration

e. Analytical specificity:

Negative urine was spiked one at a time with the possible interfering substances with concentrations listed in the following table. Each urine sample was tested with 5 replicates of the ACON Urinalysis Reagent Strips. Results were read by comparing color reaction to the color blocks on the canister label according to the Instructions on the package insert.

The following potentially interfering substances at concentrations indicated were added to the urine:

Interference Substance	Interference substances Conc. (mg/dL)	Testing Results	
		Negative urine without spiked interference substance	Negative urine with spiked interference substance
Acetoacetate	250	Negative	Positive for Ketone but Negative for others
Ammonium Chloride	200	Negative	Negative
Albumin	1,000	Negative	Positive for Protein but Negative for others
Ascorbic Acid	200	Negative	Positive for Ascorbic acid but Negative for others
Bilirubin	4	Negative	Positive for Bilirubin but Negative for others
Calcium Chloride	80	Negative	Negative
Citric Acid	65	Negative	Negative
Creatinine	600	Negative	Negative
Glucose	4,100	Negative	Positive for Glucose but Negative for others
Glycine	450	Negative	Negative
Hemoglobin	5	Negative	Positive for Blood but Negative for others
KCl	1,200	Negative	SG ↑ but Negative for others
NaCl	1,800	Negative	SG ↑ but Negative for others
Oxalic Acid	70	Negative	Negative
Phenolphthalein	1,200	Negative	Negative
Sodium Nitrate	0.3	Negative	Negative
Sodium Nitrite	10	Negative	Positive for Nitrite but Negative for others
Sodium Phosphate	500	Negative	pH ↑ but Negative for others
Theophylline	100	Negative	Negative
Urea	4,000	Negative	Negative
Fructose	1.2	Negative	Negative
Galactose	0.5	Negative	Negative
Lactose	1	Negative	Negative

The sponsor also performed interference studies that were analytes that the urinalysis strips detect in order to determine if an analyte is detected by the strip is abnormally high will it affect the results of other test pads on the strip. Urine samples were spiked with different analytes to the known concentrations which were then confirmed as positive urine samples by Bayer Multistix 10 SG Reagent Strips and Clinitek Status Analyzer. These positive urine samples were then spiked with possible interfering substances, one at a time to the levels listed in the following tables. The urine samples were tested with the ACON Urinalysis Reagent Strips in 5 replicates. Results were read by comparing color reaction

to the color blocks on the canister label according to the Instructions on the package insert.

Acceptance Criteria

The reagent pad must produce expected color-reaction when testing with the corresponding spiked samples.

The Effect of Ascorbic Acid on ACON Glucose Reagent Strip

Ascorbic Acid Concentration (mg/dL)	Glucose Concentration (mg/dL) Test Results on 5 Replicates				
	Negative	100	250	500	1,000
0	N	100*	250	500	1,000
10	N	100	250	500	1,000
25	N	N(1)** - 100(4)**	250	500	1,000
30	N	N	100	500	1,000

* 5 Replicates

** 1 tested at negative level and 4 tested at 100 mg/dL level

Ascorbic acid concentrations of 25 mg/dL or greater may reduce the sensitivity of the test.

The Effect of Acetoacetic Acid on ACON Glucose Reagent Strip

Acetoacetic Acid Concentration (mg/dL)	Glucose Concentration (mg/dL) Test Results on 5 Replicates					
	Negative	100	250	500	1,000	2,000
0	N	100	250	500	1,000	2,000
80	N	100	250	500	1,000	2,000
100	N	N(1) - 100(4)	100	250	500	1,000
120	N	N	100	250	500	1,000
140	N	N	100	250	500	1,000

Acetoacetic acid concentration of 100 mg/dL or higher decreases the sensitivity of the test.

The Effect of Specific Gravity on ACON Glucose Reagent Strip

Specific Gravity	Glucose Concentration (mg/dL)					
	Test Results on 5 Replicates					
	Negative	100	250	500	1,000	2,000
1.005	N	100	250	500	1,000	2,000
1.010	N	100	250	500	1,000	2,000
1.015	N	100	250	500	1,000	2,000
1.020	N	100	250	500	1,000	2,000
1.025	N	N(1) - 100(4)	100	500	1,000	2,000
1.030	N	N(1) - 100(4)	100	500	1,000	2,000

As the Specific Gravity increases to 1.025, the sensitivity of the Glucose reagent pad decreases.

The Effect of Specific Gravity on ACON Blood Reagent Strip

Specific Gravity	Blood Concentration (Cells/uL)				
	Test Results on 5 Replicates				
	Negative	10 (Trace)	25 (Small)	80 (Mod)	200 (Large)
1.005	N	10	25	80	200
1.010	N	10	25	80	200
1.015	N	10	25	80	200
1.020	N	10	25	80	200
1.025	N	10	25	80	200
1.030	N	10	25	80	200

Specific Gravity does not influence the sensitivity of the blood reagent pad.

The Effect of Ascorbic Acid on ACON Blood Reagent Strip

Ascorbic Acid Concentration (mg/dL)	Blood Concentration (Cells/uL)				
	Test results on 5 Replicates				
	Negative	10 (Trace)	25 (Small)	80 (Mod)	200 (Large)
0	N	10	25	80	200
20	N	10	10	80	200
30	N	N	10	80	200
35	N	N	10	80	200
50	N	N	N	80	200

In high levels of Ascorbic Acid, the sensitivity of the blood reagent pad decreases.

The Effect of pH on ACON Blood Reagent Strip

pH	Blood Concentration (Cells/uL)				
	Test results on 5 Replicates				
	Negative	10 (Trace)	25 (Small)	80 (Mod)	200 (Large)
5.0	N	+/-	+	2+	3+
6.0	N	+/-	+	2+	3+
7.0	N	+/-	+	2+	3+
7.5	N	+/-	+	2+	3+
8.0	N	+/-	+/-	2+	3+
9.0	N	N	+/-	2+	3+

As the pH increases to 8.0, the sensitivity of the blood reagent pad decreases.

The Effect of Ascorbic Acid on ACON Bilirubin Reagent Strip

Ascorbic Acid Concentration (mg/dL)	Bilirubin Concentration			
	Test Results on 5 Replicates			
	Negative	Small	Moderate	Large
0	N	S	M	L
25	N	S	M	L
30	N	N	S	L
40	N	N	S	L

As the Ascorbic Acid increases to 30 mg/dL, the sensitivity of the bilirubin reagent pad decreases.

The Effect of Acetone on ACON Ketone Reagent Strip

Acetone Concentration (mg/dL)	Ketone
	Test Results on 5 Replicates
100	No Color Changed on Strips
500	No Color Changed on Strips
10,000	No Color Changed on Strips

Acetone does not influence the Ketone reagent pad.

The Effect of Specific Gravity on ACON Nitrite Reagent Strip

Standard Material Specific Gravity	Nitrite Concentration (mg/dL)			
	Test Results on 5 Replicates			
	Negative	0.05	0.1	1.0
1.005	N	P	P	P
1.010	N	P	P	P
1.015	N	P	P	P
1.020	N	P	P	P
1.025	N	P	P	P
1.030	N	N	P	P

As the Specific Gravity increases to 1.030 or over, the sensitivity (accuracy) of the Nitrite reagent pad decreases.

The Effect of Ascorbic Acid on ACON Nitrite Reagent Strip

Ascorbic Acid (mg/dL)	Nitrite Concentration (mg/dL)			
	Test Results on 5 Replicates			
	Negative	0.05	0.1	0.5
0	N	P	P	P
25	N	P	P	P
30	N	N	P	P
35	N	N	P	P

In high levels of Ascorbic acid, the sensitivity of the Nitrite reagent pad decreases.

The Effect of pH on ACON Nitrite Reagent Strip

pH	Nitrite Concentration (mg/dL)			
	Test Results on 5 Replicates			
	Negative	0.05	0.1	1.0
5.0	N	P	P	P
6.0	N	P	P	P
7.0	N	P	P	P
7.5	N	P	P	P
8.0	N	P	P	P
9.0	N	P	P	P

The pH value does not influence the sensitivity of the Nitrite reagent pad.

The Effect of Specific Gravity on ACON Protein Reagent Strip

Specific Gravity	Protein Concentration (mg/dL)					
	Test Results on 5 Replicates					
	Negative	15	30	100	300	2,000
1.005	N	15	30	100	300	2,000
1.010	N	15	30	100	300	2,000
1.015	N	15	30	100	300	2,000
1.020	N	15	30	100	300	2,000
1.025	N	N	30	100	300	2,000
1.030	N	N	30	100	300	2,000

As the Specific Gravity increases to 1.025, the sensitivity of the Protein reagent pad decreases.

The Effect of pH on ACON Protein Reagent Strip

pH	Protein Concentration (mg/dL)					
	Test Results on 5 Replicates					
	Negative	15	30	100	300	2,000
5.0	N	15	30	100	300	2,000
6.0	N	15	30	100	300	2,000
7.0	N	15	30	100	300	2,000
7.5	N	15	30	100	300	2,000
8.0	N	15	30	100	300	2,000
9.0	N	30	100	300	300	2,000

As the pH increases to 9.0, the accuracy of the Protein reagent pad decreases.

The Effect of pH on ACON Leukocyte Reagent Strip

pH	Leukocyte Concentration (Leu/uL)				
	Test Results on 5 Replicates				
	Negative	15	70	125	500
5.0	N	15	70	125	500
6.0	N	15	70	125	500
7.0	N	15	70	125	500
7.5	N	15	70	125	500
8.0	N	15	125	500	500
9.0	N	70	125	500	500

As the pH increases to 9.0, the sensitivity of the Leukocyte reagent pad increases.

The Effect of Glucose on ACON Leukocyte Reagent Strip

Glucose Concentration (mg/dL)	Leukocyte Concentration (Leu/uL)				
	Test Results on 5 Replicates				
	Negative	15	70	125	500
0	N	15	70	125	500
1,000	N	15	70	125	500
2,000	N	N	70	125	500
4,000	N	N	70	125	500

As the concentration of Glucose increases to 2,000 mg/dL, the sensitivity of the Leukocyte reagent pad decreases.

The Effect of Specific Gravity on ACON Leukocyte Reagent Strip

Specific Gravity	Leukocyte Concentration (Leu/uL)				
	Test Results on 5 Replicates				
	Negative	15	70	125	500
1.005	N	15	70	125	500
1.010	N	15	70	125	500
1.015	N	15	70	125	500
1.020	N	15	70	125	500
1.025	N	N	70	125	500
1.030	N	N	15	125	500

As the specific gravity increases to 1.025 and over, the accuracy of the Leukocyte reagent pad decreases.

The effect of Protein (Human Albumin) on ACON Leukocyte Reagent Strip

Human Albumin Concentration (mg/dL)	Leukocyte Concentration (Leu/uL)				
	Test Results on 5 Replicates				
	Negative	15	75	125	500
0	Neg	15	75	125	500
500	Neg	15	75	125	500
1,000	Neg	Neg	75	125	500
1,500	Neg	Neg	75	125	500

As protein concentration increases to 1,000 mg/dL, the sensitivity of the Leukocyte reagent pad decreases.

The Effect of Nitrite on ACON Urobilinogen Reagent Strip

Nitrite Concentration (mg/dL)	Urobilinogen Concentration (mg/dL)					
	Test Results on 5 Replicates					
	0.2	1.0	2.0	4.0	8.0	12
0	0.2	1.0	2.0	4.0	8.0	12
1	0.2	1.0	2.0	4.0	8.0	12
10	0.2	1.0	2.0	4.0	8.0	12
20	0.2	1.0	2.0	4.0	8.0	12

The concentrations of Nitrite tested do not influence the accuracy of the Leukocyte reagent pad.

The Effect of pH on ACON Specific Gravity Reagent Strip

pH	Specific Gravity						
	Test Results on 5 Replicates						
	1.000	1.005	1.010	1.015	1.020	1.025	1.030
4.5	1.005	1.010	1.015	1.020	1.025	1.030	1.030
5	1.000	1.005	1.010	1.015	1.020	1.025	1.030
6	1.000	1.005	1.010	1.015	1.020	1.025	1.030
6.5	1.000	1.005	1.010	1.015	1.020	1.025	1.030
7	1.000	1.005	1.010	1.015	1.020	1.025	1.030
7.5	1.000	1.005	1.010	1.010	1.015	1.020	1.025
8	1.000	1.005	1.005	1.010	1.015	1.020	1.025
8.5	1.000	1.005	1.005	1.010	1.015	1.020	1.025
9	1.000	1.000	1.005	1.010	1.015	1.020	1.025

As the pH is higher than 7.5, the sensitivity of the Specific Gravity reagent pad decreases 0.005. As the pH is less than 5, the sensitivity of the Specific Gravity reagent pad increases 0.005.

The Effect of Protein on ACON Specific Gravity Reagent Strip

Protein Concentration (mg/dL)	Specific Gravity					
	Test Results on 5 Replicates					
	1.005	1.010	1.015	1.020	1.025	1.030
0	1.005	1.010	1.015	1.020	1.025	1.030
80	1.005	1.010	1.015	1.020	1.025	1.030
100	1.005	1.010	1.015	1.020	1.025	1.030
300	1.010	1.015	1.015	1.020	1.025	1.030
500	1.015	1.015	1.015	1.020	1.025	1.030
1,000	1.015	1.015	1.015	1.020	1.025	1.030
1,500	1.015	1.015	1.015	1.020	1.025	1.030

As the concentration of protein increases to 300 mg/dL, the accuracy of the Specific Gravity reagent pad decreases.

The Effect of Glucose on ACON Specific Gravity Reagent Strip

Glucose Concentration (mg/dL)	Specific Gravity
	Test Results on 5 Replicates
0	1.015
1,000	1.015
2,000	1.015
4,000	1.015

The test results on the Specific Gravity reagent pad are not affected by Glucose levels tested.

The sponsor also examined the effect of excess urine sample “runover” phenomenon between pH and Protein pads when the excess urine was not removed immediately. The pH standard solutions, 5.0, 6.0, 7.0, 8.0 and 9.0, prepared with fresh negative urine were used in the study.

Testing protocol #1: Dip the ACON Urinalysis Reagent Strips into standard urine solutions and take out immediately, remove excess urine from the strips right away according to the package insert. Read results in the scheduled time. Tests were repeated 10 times for each solution.
Testing protocol #2: Dip the strips into standard urine solutions and take out immediately, did not remove excess urine from the strips. Read results in the

scheduled time. Tests were repeated 10 times for each solution.

Testing was performed and results were determined visually by comparing the reaction colors with the color chart. Results were summarized in the following table.

pH	Expected Results	**Test Results with Excess Urine Sample Removed**			**Test Results without Excess Urine Sample Removed**		
		Testing Results	Percent Agreement	Percent Disagreement	Testing Results	Percent Agreement	Percent Disagreement
5.0	5.0	10 @ 5.0	100%	0%	10 @ 5.0	100%	0%
6.0	6.0	10 @ 6.0	100%	0%	10 @ 6.0	100%	0%
7.0	7.0	10 @ 7.0	100%	0%	7 @ 7.0 3 @ 6.5	70%	30%
8.0	8.0	10 @ 8.0	100%	0%	6 @ 8.0 3 @ 7.0 1 @ 5.0	60%	40%
9.0	9.0	10 @9.0	100%	0%	7 @ 9.0 2 @ 8.0 1 @ 5.0	70%	30%

From the testing results, if the excess urine was not removed immediately, the edge of pH reagent pad became red as the result of the acidic component runover from the Protein pad onto the pH pad.

The sponsor also indicates that urinalysis reagent strips may be affected by substances that cause abnormal urine color such as drugs containing azo dyes (e.g. Pyridium®, Azo Gantrisin®, Azo Gantanol®), nitrofurantoin (Microdantin®, Furadantin®), and riboflavin. The color development on the test pad may be masked or a color reaction may be produced that could be interpreted as false results. In addition, the sensitivity of the Nitrite pad is reduced for urine specimens with highly buffered alkaline (e.g. Sodium Bicarbonate).

f. Assay cut-off:
See Detection Limit above.

2. Comparison studies:

a. Method comparison with predicate device:

The sponsor performed a consumer study consisting of 125 professionals (the intended users of the device) to determine how results recoded by users correlated with results read on the predicate device. The study was performed at 3 different clinical sites, and the 125 samples were tested among the 3 sites, 72 samples at the first, 42 samples at the second, and 11 samples from the third. Results from 125 urine specimens were tested and recorded with the results outlined below.

Comparison of Total Agreements Within +/- One Color Block	**Leukocyte**	
	Observed # of Correct Results Within +/- 1 Color Block	Expected # of Correct Results Within +/- 1 Color Block
ACON (Visual) vs. Bayer (Visual)	121	125
ACON (Visual) vs. Bayer (Instrument)	122	125
Bayer (Visual) vs. Bayer (Instrument)	122	125

Comparison of Total Agreements Within +/- One Color Block	**Nitrite**	
	Observed # of Correct Results Within +/- 1 Color Block	Expected # of Correct Results Within +/- 1 Color Block
ACON (Visual) vs. Bayer (Visual)	124	125
ACON (Visual) vs. Bayer (Instrument)	125	125
Bayer (Visual) vs. Bayer (Instrument)	125	125

Comparison of Total Agreements Within +/- One Color Block	**Urobilinogen**	
	Observed # of Correct Results Within +/- 1 Color Block	Expected # of Correct Results Within +/- 1 Color Block
ACON (Visual) vs. Bayer (Visual)	124	125
ACON (Visual) vs. Bayer (Instrument)	125	125
Bayer (Visual) vs. Bayer (Instrument)	123	125

Comparison of Total Agreements Within +/- One Color Block	**Protein**	
	Observed # of Correct Results Within +/- 1 Color Block	Expected # of Correct Results Within +/- 1 Color Block
ACON (Visual) vs. Bayer (Visual)	118	125
ACON (Visual) vs. Bayer (Instrument)	110	125
Bayer (Visual) vs. Bayer (Instrument)	118	125

Comparison of Total Agreements Within +/- One Color Block	**pH**	
	Observed # of Correct Results Within +/- 1 Color Block	Expected # of Correct Results Within +/- 1 Color Block
ACON (Visual) vs. Bayer (Visual)	103	125
ACON (Visual) vs. Bayer (Instrument)	89	125
Bayer (Visual) vs. Bayer (Instrument)	109	125

Comparison of Total Agreements Within +/- One Color Block	**Blood**	
	Observed # of Correct Results Within +/- 1 Color Block	Expected # of Correct Results Within +/- 1 Color Block
ACON (Visual) vs. Bayer (Visual)	121	125
ACON (Visual) vs. Bayer (Instrument)	120	125
Bayer (Visual) vs. Bayer (Instrument)	118	125

Comparison of Total Agreements Within +/- One Color Block	**Specific Gravity**	
	Observed # of Correct Results Within +/- 1 Color Block	Expected # of Correct Results Within +/- 1 Color Block
ACON (Visual) vs. Bayer (Visual)	117	125
ACON (Visual) vs. Bayer (Instrument)	98	125
Bayer (Visual) vs. Bayer (Instrument)	104	125

Comparison of Total Agreements Within +/- One Color Block	**Ketone**	
	Observed # of Correct Results Within +/- 1 Color Block	Expected # of Correct Results Within +/- 1 Color Block
ACON (Visual) vs. Bayer (Visual)	125	125
ACON (Visual) vs. Bayer (Instrument)	123	125
Bayer (Visual) vs. Bayer (Instrument)	124	125

Comparison of Total Agreements Within +/- One Color Block	**Bilirubin**	
	Observed # of Correct Results Within +/- 1 Color Block	Expected # of Correct Results Within +/- 1 Color Block
ACON (Visual) vs. Bayer (Visual)	124	125
ACON (Visual) vs. Bayer (Instrument)	123	125
Bayer (Visual) vs. Bayer (Instrument)	125	125

Comparison of Total Agreements Within +/- One Color Block	**Glucose**	
	Observed # of Correct Results Within +/- 1 Color Block	Expected # of Correct Results Within +/- 1 Color Block
ACON (Visual) vs. Bayer (Visual)	124	125
ACON (Visual) vs. Bayer (Instrument)	124	125
Bayer (Visual) vs. Bayer (Instrument)	124	125

The sponsor also compared the pH of the ACON Urinalysis Reagent Strips to the Bayer Multistix 10 SG Urine Strips using two different methods:

Method #1: Seven pH standard solutions (pH from 5.02 to 9.0) were tested with the Bayer Multistix 10 SG Urine Strips and the ACON Urinalysis Reagent Strips, respectively, according to their package inserts. Results are summarized in the table below.

Method #1:

pH Meter	5.02	6.01	6.49	7.0	7.51	8.0	9.0
ACON	5.0	6.0	6.5	7.0	7.5	8.0	9.0
Bayer	5.0	6.0	7.0	7.0	8.0	8.0	8.5*

* Bayer color chart doesn't have the color block for pH 9.0.

Method #2: 47 clinical urine samples were tested with the Bayer Multistix 10 SG Urine Strips, the ACON Urinalysis Reagent Strips according to their package inserts together with a pH meter. Results are summarized in the table below.

Method #2:

The differences between urine strips and pH meter results are presented below:

Result Differences Between pH Meter and Urine Strips	< 0.5	> 0.5	Mean ± SD (Differences Between pH Meter and Strip Results)
ACON Urinalysis Reagent Strips	47/47	0/47	0.180 ± 0.162
Bayer Multistix 10 SG Reagent Strips for Urinalysis	35/47	12/47	0.334 ± 0.242

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):
See Method Comparison section above.

4. Clinical cut-off:
Not applicable.

5. Expected values/Reference range:

The package insert goes into detail on interpretation of expected values with citations of literature. The statements made are summarized below.

Urobilinogen: 0.2-1.0 mg/dL (3.5-17 μmol/L)
Glucose: < Trace
Bilirubin: < Trace
Ketones: 0 mg/dL
pH: The expected range for other normal urine specimens is pH 4.5-8, with an average result of pH 6. For newborns pH 5-7 is expected.
Blood: < Trace
Specific Gravity (SG): 1.016-1.022.
Protein: 1-14 mg/dL
Nitrite: 0 mg/dL
Leukocyte: Negative
Ascorbic acid: urinary output of 2 – 10 mg/dL daily

N. Proposed Labeling:

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

O. Conclusion:

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