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

A. 510(k) Number:

k070929

B. Purpose for Submission:

New submission for the ACON™ U120 Urine Analyzer for the use with ACON Laboratories previously cleared urine strips, ACON Urinalysis Reagent Strips k061559.

C. Measurand:

Glucose, Blood, Leukocytes, Specific Gravity, pH, Nitrite, Protein, Ketone, Urobilinogen, Ascorbic Acid and Bilirubin in urine

D. Type of Test:

Qualitative

E. Applicant:

ACON Laboratories, Inc.

F. Proprietary and Established Names:

ACON™ U120 Urine Analyzer

G. Regulatory Information:

1. Regulation section:

21 CFR § 862.2900	Automated urinalysis system
21 CFR § 862.1340	Urinary glucose (nonquantitative) test system
21 CFR § 864.6550	Occult blood test
21 CFR § 864.7675	Leukocyte peroxidase test
21 CFR § 862.2800	Refractometer for clinical use
21 CFR § 862.1550	Urinary pH (nonquantitative) test system
21 CFR § 862.1510	Nitrite (nonquantitative) test system
21 CFR § 862.1645	Urinary protein or albumin (nonquantitative) test system
21 CFR § 862.1435	Ketones (nonquantitative) test system
21 CFR § 862.1785	Urinary urobilinogen (nonquantitative) test system

21 CFR § 862.1115   Urinary bilirubin and its conjugates (nonquantitative) test system
21 CFR § 862.1095   Ascorbic Acid test system

2. Classification:

Class II; Urinary glucose (nonquantitative) test system and Occult blood test

Class I; Leukocyte peroxidase test, Refractometer for clinical use, Urinary pH (nonquantitative) test system, Nitrite (nonquantitative) test system, Urinary protein or albumin (nonquantitative) test system, Ketones (nonquantitative) test system, Urinary urobilinogen (nonquantitative) test system and Urinary bilirubin and its conjugates (nonquantitative) test system, Automated urinalysis system and Ascorbic Acid test system

3. Product code:

KQO, JIL, JIO, LJX, JRE, CEN, JMT, JIR, JIN, CDM. JJB AND JMA, respectively

4. Panel:

75 Chemistry and 81 Hematology

H. Intended Use:

1. Intended use(s):

See Indications for use below.

2. Indication(s) for use:

The ACON™ U120 Urine Analyzer is intended for use in conjunction with the ACON 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 professional, 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.

3. Special conditions for use statement(s):

For prescription use only

4. Special instrument requirements:

ACON™ U120 Urine Analyzer

I. Device Description:

The analyzer is composed of an internal Processor with memory, mechanical unit, liquid crystal display (LCD), photoelectric scanning unit, power system, keyboard, 25 pin parallel external printer port, internal printer and standard RS-232C port.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Bayer Clinitek Status Urine Chemistry Analyzer, Bayer Healthcare, LLC

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

   k031947

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Specimen	Urine	Same
Methodology	Reflectance Photometer	Same
Strip Incubation Time	1 minute	Same
Line Leakage Current	<0.5 mA	Same

Differences		
Item	Device	Predicate
Parameters Detected	Leukocytes, Nitrite, Blood (Occult), Glucose, Protein, Ketone, Specific Gravity, pH, Bilirubin, Urobilinogen and Ascorbic Acid	Leukocytes, Nitrite, Blood (Occult), Glucose, Albumin, Protein, Creatinine, Ketone, Specific Gravity, pH, Bilirubin, Urobilinogen and hCG
Strips or Cassette to be Used	ACON Urinalysis Reagent Strips	Bayer Urinalysis Strips or hCG Cassette
Detection	Photosensitive diode	CCD
Throughput	Single Test Mode: 40 tests/hour, Continuous Test Mode: 120 test/hour	60 test/hour
Memory	Last 500 results	200 results

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

IE/CEN 61326

L. Test Principle:

The U120 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 photodiode as a light sensor, the optical system reads the color change in the urine test strips after a sample is applied.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

   a. *Precision/Reproducibility:*

   The precision evaluation included 10 replications on two levels of controls, using three instruments and three lot numbers. The contingency table 2x2 is applied to evaluate the total agreement, in term of percentage, on each parameter. The expected values of the control material were used to determine the agreement between the samples.

Urine analyte	Expected values Control level I and II	Expected result(s) determined by Comparator Method	Acon U120 results	% Agreement with expected results	n
GLU	Neg	Negative	Negative	100	900
GLU	250 - ≥ 2000	500	500	100	900
BILI	Neg	Negative	Negative	100	900
BILI	Mod. - Large	Large	Large	100	900
KET	Neg	Negative	Negative	100	900
KET	5 – 40	40	15	100 within 1 color block	900
SG	1.010 - 1.020	1.020	1.020	100	900
SG	1.015 – 1.025	1.015	1.015	100	900
BLO	Neg	Negative	Negative	100	900
BLO	Mod. - Large	Large	Large	100	900
pH	5.0 – 6.0	5.0	5.0	100	900
pH	6.5 – 7.5	7.0	7.0	100	900
PRO	Neg	Negative	Negative	100	900
PRO	30 - ≥ 300	300	300	100	900
URO	0.2 – 1.0	0.2	0.2	100	900
URO	4.0 – 8.0	8.0	8.0	100	900
NIT	Neg	Negative	Negative	100	900
NIT	Positive	Positive	Positive	100	900
LEU	Neg	Negative	Negative	100	900
LEU	Small - Large	Large	Large	100	900
ASC	Neg	Negative	Negative	100	900

The urinalysis controls did not contain ascorbic acid; the sponsor used one ascorbic acid standard positive solution, 20 mg/dL. Test was performed as above.

Urine analyte	Expected values Ascorbic Acid Standard	Expected result(s) determined by Comparator Method	Acon U120 results	% Agreement with expected results	n
ASC	20	N/A	20	100	900

b. *Linearity/assay reportable range:*

See the Method Comparison section 2.a below

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

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d. *Detection limit:*

The sensitivity of the assay when read by the ACON U120 Urine Analyzer 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 80%, 60% of the originals with negative urine. Each urine sample was tested with three lots of the ACON Urinalysis Reagent Strips on three analyzers. For three consecutive days, each sample was tested 15 times per day. A total of 135 strips were used for each concentration tested (3 analyzers x 3 days x 5 strips x 3 lots = 135 strips). The minimum sensitivity level for each analyte of the ACON Urinalysis Reagent Strips when read by the analyzer is defined by the sponsor as the lowest level at which over 55% 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.

Analyte	Detection Range of ACON U120 Urine Analyzer	Minimum Sensitivity
Glucose	0, 100, 250, 500 &1,000 mg/dL	80 mg/dL
Bilirubin	0, 1, 2 & 4 mg/dL	0.8 mg/dL
Ketone	0, 5, 15, 40 & 80 mg/dL	4 mg/dL
Blood	0, 10, 25, 80 & 200 Cells/μL	5 Cells/μL
Protein	0, 15, 30, 100 & 300 mg/dL	12 mg/dL
Urobilinogen	0.2, 1, 2, 4 & 8 mg/dL	0.8 mg/dL
Nitrite	Negative, Positive	0.05 mg/dL
Leukocyte	0, 15, 70, 125 & 500 Cells/μL	12 Cells/μL
Ascorbic Acid	0, 10, 20 & 40 mg/dL	8 mg/dL
pH	5, 5.5, 6, 6.5, 7.0, 7.5, 8.0, 8.5 & 9.0	5
Specific Gravity	1.000, 1.005, 1.010, 1.015, 1.020, 1.025 & 1.030	1.000

e. *Analytical specificity:*

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f. *Assay cut-off:*

See detection limit section M.1.d above

2. Comparison studies:

a. *Method comparison with predicate device:*

Patient samples were tested in three Point of Care settings on both the Acon U120 analyzer and Bayer Clinitek Status using the respective reagent strips for each system. Spiked samples covering the range of each analyte were tested in-house by the sponsor.

Glucose:

	U120 ≥1,000	500	250	100	0 (Neg)
Predicate					
≥1,000	45				
500		43	3		
250			41	4	
100				47	2
0 (Neg)			1	5	163
Total	45	43	45	56	165
% Agreement (Exactly Match)	100	100	91	84	99
% Agreement (±1 Color Block)	100	100	98	100	100

Bilirubin:

	U120 4 (+++)	2 (++)	1 (+)	0 (Neg)
Predicate				
+++	44	1		
++		44	3	1
+			46	10
0 (Neg)		1	4	155
Total	44	46	53	166
% Agreement (Exactly Match)	100	96	87	93
% Agreement (±1 Color Block)	100	98	100	99

Ketone:

	U120 80	40	15	5	0 (Neg)
Predicate					
80	45	1			
40		45			
15			43	6	
5				55	13
0 (Neg)				5	141
Total	45	46	43	66	154
% Agreement (Exactly Match)	100	98	100	83	92
% Agreement (±1 Color Block)	100	100	100	100	100

SG:

	U120 1.030	1.025	1.020	1.015	1.010	1.005	1.000
Predicate							
1.030	85	4					
1.025	7	59	2	2			
1.020	5	14	50	6	1		
1.015		5	4	53	1		
1.010			3	3	45	1	
≤1.005					4	45	45
Total	97	82	59	64	51	46	45
% Agreement (Exactly Match)	88	72	85	83	88	98	100
% Agreement (±1 Color Block)	95	94	95	97	98	100	100

Blood:

U120	+++	++	+	+/-	0 (Neg)
Predicate					
+++	48	1			
++		47			1
+		4	48	3	1
+/-			1	49	19
0 (Neg)					132
Total	48	52	49	52	153
% Agreement (Exactly Match)	100	90	98	94	86
% Agreement (±1 Color Block)	100	100	100	100	99

pH:

U120	9.0	8.5	8.0	7.5	7.0	6.5	6.0	≤5.5
Predicate								
8.5	45*	43	3	1				
8.0			42	3	1	1		
7.5			1	47	2			1
7.0				1	51	6	1	5
6.5					1	42	4	7
6.0			1				45	22
≤5.5						2	1	110
Total	45	43	47	52	55	51	51	145
% Agreement (Exactly Match)	100	100	89	90	93	82	88	76
% Agreement (±1 Color Block)	100	100	98	98	98	94	98	91

*The highest pH detection range of the predicate, Bayer Clinitek Analyzer, is 8.5.

Protein:

U120	≥300	100	30	15	0 (Neg)
Predicate					
≥300	47				
100	1	45	4		
30			46	11	8
15			1	51	12
0 (Neg)				6	122
Total	48	45	51	68	142
% Agreement (Exactly Match)	98	100	90	75	86
% Agreement (±1 Color Block)	100	100	100	100	94

Urobilinogen:

U120	8	4	2	1	0 (Neg)
Predicate					
8	45				
4		45			
2		6	39		
1				41	11
0 (Neg)				2	165
Total	45	51	39	43	176
% Agreement (Exactly Match)	100	88	100	95	94
% Agreement (±1 Color Block)	100	100	100	100	100

Nitrite:

U120	Positive	Negative
Predicate		
Positive	137	5
Negative	1	166
Total	138	171
% Agreement (Exactly Match)	99	97
% Agreement (±1 Color Block)	100	100

Leukocyte:

	U120 500	125	70	15	0 (Neg)
Predicate					
500 (+++)	48				
125 (++)		45			
70 (+)		1	46	1	
15 (Trace)		1	2	51	4
0 (Neg)			1	10	144
Total	48	47	49	62	148
% Agreement (Exactly Match)	100	96	94	82	97
% Agreement (±1 Color Block)	100	98	98	100	100

b. *Matrix comparison:*

Not applicable. The device is only intended for measurements with urine samples.

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:

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N. Instrument Name:

Acon U120 Urine Analyzer

O. System Descriptions:

1. Modes of Operation:

   Single and continuous testing mode

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:

   Manual Patient ID entry

4. Specimen Sampling and Handling:

   Single Step or Continuous Test Modes the strip is manual dip and the strip is place on the strip holder.

5. Calibration:

   The reflectance of the white calibration circle located on the top of the strip holder is tested when the instrument is first turned on and with each test strip.

6. Quality Control:

   Recommendations for testing quality control are provided in the labeling as follows: users should follow federal, state and local requirements for quality control testing.

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

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.