

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

A. 510(k) Number:

k083724

B. Purpose for Submission:

New device

C. Measurand:

Glucose, blood, leukocytes, specific gravity, pH, nitrite, protein, ketone, urobilinogen, ascorbic acid and bilirubin in urine

D. Type of Test:

Qualitative and semi-quantitative visual read

E. Applicant:

Wiener Laboratorios S.A.I.C.

F. Proprietary and Established Names:

Wiener lab. Urine Strip

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
JIL-Urinary glucose (nonquantitative) test system	II	21 CFR§ 862.1340	75, Chemistry
JIO-Occult blood test	II	21 CFR§ 864.6550	81 Hematology
LJX-Leukocyte peroxidase test	I	21 CFR§ 864.7675	81 Hematology
CEN-Urinary pH (nonquantitative) test system	I	21 CFR§ 862.1550	75Chemistry
JMT- Nitrite (nonquantitative) test system	I	21 CFR§ 862.1510	75 Chemistry
JIR-Urinary protein or albumin (nonquantitative) test system	I	21 CFR§ 862.1645	75 Chemistry

JIN-Ketones (nonquantitative) test system	I	21 CFR§ 862.1435	75 Chemistry
CDM-Urinary urobilinogen (nonquantitative) test system	I	21 CFR§ 862.1785	75 Chemistry
JJB-Urinary bilirubin and its conjugates (nonquantitative) test system	I	21 CFR§ 862.1115	75 Chemistry
JMA-Ascorbic Acid test system	I	21 CFR§ 862.1095	75 Chemistry

H. Intended Use:

1. Intended use(s):

See indications for use below.

2. Indication(s) for use:

Urine strip test strips are for “in vitro” diagnostic use and are intended for prescription use near-patient (point of care) and centralized laboratory locations. Urine Strip includes test pads for qualitative and semi-quantitative determination of urobilinogen, glucose, ketones, bilirubin, proteins, nitrite, pH, blood, specific gravity, leukocytes and ascorbic acid in urine.

Urine test strips results may provide information regarding the status of carbohydrate metabolism, kidney and liver function, acid-base balance and urinary tract infections. Test 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.

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 Wiener lab Urine Strips are in vitro diagnostic reagents strips containing dry chemicals for the qualitative and semi-quantitative detection of urobilinogen, glucose, ketones, bilirubin, proteins, nitrite, pH, blood, specific gravity, leukocytes and ascorbic acid in urine. The sample reacts with the solid phase dry chemical reagent

pads attached to a plastic holder. The results are obtained by the direct comparison of the reagent strip with the color blocks on the bottle label. The entire reagent is disposable after use. Laboratory instrumentation is not required.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Bayer Multistix 10 SG and Teco Diagnostics Clinistrip

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

k960546 and k970250, respectively

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended Use	Prescription use	Same
Intended Specimen	Urine	Same
Material Provided	Plastic strips affixed with several separate dry reagent pads.	Same
Glucose Methodology	Same	Same
Ketone Methodology	Same	Same
Specific Gravity Methodology	Same	Same
pH Methodology	Same	Same
Protein Methodology	Same	Same

Differences		
Item	Device	Predicate
Bilirubin Methodology	Based on the coupling of bilirubin with 2,4-dichlorophenyl diazonium salt in a strong acid medium	Based on the union of bilirubin and diazotized dichloroaniline in strongly acid medium

Blood Methodology	Based on the pseudoperoxidase activity of hemoglobin, which catalyzes the reaction of 3,3',5,5'-tetramethylbenzidine with buffered organic hydroperoxide	Based on the hemoglobin peroxidase like activity of hemoglobin, which catalyzes the reaction of diisopropylbenzene and hydroperoxide and 3,3',5,5'-tetramethylbenzidine
Urobilinogen Methodology	Based on the diazotization reaction of a diazonium salt and urinary urobilinogen in a strong acid medium	Based on a modified Erlich reaction in which p-diethylaminobenzaldehyde in conjunction with a color enhancer reacts with urobilinogen in a strongly acidic medium
Nitrite Methodology	Based on the reaction of the p-arsanilic acid and nitrite, derived from a dietary nitrite in the presence of bacteria in urine, to form a diazonium compound. This compound reacts with N(-1-naphthyl)-ethylenediamine in an acidic medium.	Based on the reaction of urinary nitrite and p-arsenilic acid, forming a diazonium compound. This compound reacts with 1,2,3,4-tetrahydrobenzo(h)quinoline-3-ol
Leukocytes Methodology	Based on the presence of granulocyte esterases. The esterases cleave a pyrazol ester derivate to release hydroxypyrazol derivative. This derivative reacts with diazonium salt to produce a purple product	Granulocyte leukocytes contain esterases that catalyze the hydrolysis of the derivatized pyrrole that react with diazonium salt to produce a purple color.
Working Temperature Range	< 30°C	15 to 30°C
Storage Time	60 seconds-2 minutes	30 seconds -2 minutes

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

None were referenced.

L. Test Principle:

Glucose: is based on a sequential enzyme reaction. First, glucose oxidase catalyzes the formation of gluconic acid and hydrogen peroxide from the oxidation of glucose. Then,

peroxidase catalyzes the reaction of hydrogen peroxide with potassium iodide to colors ranging from greenish light-blue through greenish-brown and then to brown.

Bilirubin: is based on the coupling of bilirubin with 2,4-dichlorophenyl diazonium salt in a strong acid medium. The color changes from light tan to dark-tan.

Ketone: is based on the reaction of acetoacetic acid in urine with nitroprusside. The resulting color ranges from tan, when no reaction takes place, different purple shades for positive reactions.

Specific Gravity: is based on the pKa change. In the presence of urinary cations, protons are released from a polyelectrolyte producing a color change in the bromothymol blue indicator from blue to yellow.

Blood: is based on the pseudoperoxidase activity of hemoglobin, which catalyzes the reaction of 3,3',5,5'-tetramethylbencidine with buffered organic hydroperoxide. The resulting color ranges from greenish-yellow to greenish-blue and then to dark blue.

pH: is based on a double indicators (methyl red and bromothymol blue), which gives a broad range of colors covering the entire urinary pH range. The colors range from orange to greenish-yellow and then to bluish-green.

Protein: is based on the color change of the indicator, tetrabromophenol, in the presence of proteins. A positive reaction is indicated by a color change from greenish-yellow to green and then to dark-green.

Urobilinogen: is based on the diazotization reaction of a diazonium salt and urinary urobilinogen in a strong acid medium. The color changes range from light-pink to dark reddish-pink.

Nitrite: is based on the reaction of the p-arsanilic acid and nitrite, derived from a dietary nitrate in the presence of bacteria in urine, to form a diazonium compound. This compound reacts with N-(1-naphthyl)-ethylenediamine in an acidic medium. The resulting color is pink. Any degree of pink color is considered positive.

Leukocytes: reveals the presence of granulocyte esterases. The esterases cleave a pyrazole ester derivative to release hydroxyrazol derivative. This derivative reacts with diazonium salt to produce a purple product.

Ascorbic acid: is based on the reducing process of ascorbic acid. The composition comprises certain aromatic compound which is colored in its oxidized state but which becomes colorless when reduced by ascorbic acid. The color changes from dark-green to greenish-yellow.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

Reproducibility testing was performed using 2 commercially available urine controls (negative and a positive). Within-run precision was performed in 20 replicates in one day with three lots and three operators. The between-run assayed both controls once a day for 20 days using three lots and three operators. The results were read by comparing color reactions to the color blocks on the canister label. Results are displayed in the table below:

Analyte	Control Level I (negative)			Control Level II (positive)		
	Expected Results	Within-run Total Agreement	Between-day Total Agreement	Expected Results mg/dL	Within-run Total Agreement	Between-day Total Agreement
Urobilinogen	0.1 mg/dL	58/60 (96.7%)	56/60 (93%)	2	57/60 (95%)	53/60 (88.3%)
Glucose	Negative	60/60 (100%)	58/60 (96.7%)	500	56/60 (93.3%)	56/60 (93.3%)
Ketones	Negative	57/60 (95%)	54/60 (90%)	15	57/60 (95%)	55/60 (91.7%)
Bilirubin	Negative	56/60 (93%)	55/60 (91.7%)	3+	59/60 (98.3%)	56/60 (93.3%)
Proteins	Negative	59/60 (98.3%)	57/60 (95%)	30	57/60 (95%)	57/60 (95%)
Nitrite	Negative	60/60 (100%)	60/60 (100%)	Positive	57/60 (95%)	56/60 (93.3%)
pH	6.0	56/60 (93%)	53/60 (88.3%)	7.0	56/60 (93.3%)	52/60 (86.7%)
Blood	Negative	58/60 (96.7%)	57/60 (95%)	50 Ery/ul	57/60 (95%)	57/60 (95%)
Specific Gravity	1.020	56/60 (93.3%)	53/60 (88.3%)	1.010	57/60 (95%)	55/60 (91.7%)
Leukocytes	Negative	58/60 (96.6%)	57/60 (95%)	25 Leu/ul	57/60 (95%)	56/60 (93.3%)

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

Analyte	Control Level I (negative)			Control Level II (positive)		
	Expected Results	Within-run Total Agreement	Between-day Total Agreement	Expected Results mg/dL	Within-run Total Agreement	Between-day Total Agreement
Ascorbic Acid	Negative	57/60 (95%)	56/60 (93.3%)	20	56/60 (93.3%)	57/60 (95%)

Point-of-Care Precision Testing:

Precision studies were performed at three POL sites with three operators typically found in these settings. Three lots of test strips were used (one at each site). Testing was performed using 2 commercially available urine controls (negative and a positive). The urinalysis controls did not contain

ascorbic acid; the sponsor used one ascorbic acid positive standard solution, which contained 20 mg/dL. Within-run precision was performed in 20 replicates in one day with three lots and three operators. The between-run assayed both controls once a day for 20 days. The results were read by comparing color reactions to the color blocks on the canister label. Results are displayed in the table below:

Control 1 (Negative)						
Analyte	Expected Results		Site 1 Total Agreement	Site 2 Total Agreement	Site 3 Total Agreement	Combined Total Agreement
Urobilinogen	0.1 mg/dl	Within-run	57/60 (95%)	58/60 (96.7%)	56/60 (93.3%)	171/180 (95%)
		Between-run	56/60 (93.3%)	57/60 (95%)	58/60 (96.7%)	171/180 (95%)
Glucose	Negative	Within-run	59/60 (98.3%)	58/60 (96.7%)	57/60 (95%)	174/180 (96.7%)
		Between-run	58/60 (96.7%)	57/60 (95%)	57/60 (93.3%)	172/180 (95.6%)
Ketones	Negative	Within-run	56/60 (93.3%)	56/60 (93.3%)	56/60 (93.3%)	168/180 (93.3%)
		Between-run	54/60 (90%)	53/60 (88.3%)	54/60 (90%)	161/180 (89.4%)
Bilirubin	Negative	Within-run	57/60 (95%)	56/60 (93.3%)	56/60 (93.3%)	169/180 (93.9%)
		Between-run	55/60 (91.7%)	56/60 (93.3%)	54/60 (90%)	165/180 (91.7%)
Protein	Negative	Within-run	58/60 (96.7%)	57/60 (95%)	57/60 (95%)	172/180 (95.6%)
		Between-run	57/60 (95%)	56/60 (93.3%)	55/60 (91.7%)	168/180 (93.3%)
Nitrite	Negative	Within-run	60/60 (100%)	59/60 (98.3%)	58/60 (96.7%)	177/180 (98.3%)
		Between-run	60/60 (100%)	58/60 (91.7%)	57/60 (95%)	175/180 (97.2%)
pH	6.0	Within-run	57/60 (95%)	56/60 (93.3%)	55/60 (91.7%)	168/180 (93.3%)
		Between-run	53/60 (88.3%)	54/60 (90%)	53/60 (88.3%)	160/180 (88.9%)
Blood	Negative	Within-run	59/60 (98.3%)	58/60 (96.7%)	57/60 (95%)	174/180 (96.7%)
		Between-run	57/60 (95%)	57/60 (95%)	56/60 (93.3%)	170/180 (94.4%)
Specific	1.020	Within-run	57/60	56/60	57/60	170/180

Gravity			(95%)	(93.3%)	(95%)	(94.4%)
		Between-run	53/60 (88.3%)	54/60 (93.3%)	55/60 (91.7%)	162/180 (90%)
Leukocytes	Negative	Within-run	57/60 (95%)	57/60 (95%)	58/60 (96.7%)	172/180 (95.6%)
		Between-run	57/60 (95%)	55/60 (91.7%)	57/60 (95%)	169/180 (93.9)
Ascorbic Acid	Negative	Within-run	58/60 (96.7%)	57/60 (95%)	56/60 (93.3%)	171/180 (95%)
		Between-run	56/60 (93.3%)	56/60 (93.3%)	55/60 (91.7%)	167/180 (92.7%)

Control 2 (Positive)						
Analyte	Expected Results		Site 1 Total Agreement	Site 2 Total Agreement	Site 3 Total Agreement	Combined Total Agreement
Urobilinogen	2.0 mg/dl	Within-run	56/60 (93.3%)	57/60 (95%)	57/60 (95%)	170/180 (94.4%)
		Between-run	53/60 (88.3%)	54/60 (90%)	55/60 (91.7%)	162/180 (90%)
Glucose	500 mg/dL	Within-run	57/60 (95%)	56/60 (93.3%)	57/60 (95%)	170/180 (94.4%)
		Between-run	56/60 (93.3%)	56/60 (93.3%)	57/60 (95%)	169/180 (93.9%)
Ketones	15 mg/dL	Within-run	57/60 (95%)	57/60 (95%)	58/60 (96.7%)	172/180 (95.6%)
		Between-run	55/60 (91.7%)	56/60 (93.3%)	55/60 (91.7%)	166/180 (92.2%)
Bilirubin	3+	Within-run	57/60 (95%)	58/60 (96.7%)	57/60 (95%)	172/180 (95.6%)
		Between-run	56/60 (93.3%)	56/60 (93.3%)	55/60 (91.7%)	167/180 (92.7%)
Protein	30 mg/dL	Within-run	57/60 (95%)	58/60 (96.7%)	57/60 (95%)	172/180 (95.6%)
		Between-run	57/60 (95%)	57/60 (95%)	56/60 (93.3%)	170/180 (94.4%)
Nitrite	Positive	Within-run	58/60 (96.7%)	57/60 (95%)	56/60 (93.3%)	171/180 (95%)
		Between-run	56/60 (93.3%)	55/60 (91.7%)	55/60 (91.7%)	166/180 (92.2%)
pH	7.0	Within-run	56/60 (93.3%)	56/60 (93.3%)	56/60 (93.3%)	168/180 (93.3%)
		Between-run	52/60 (86.7%)	54/60 (90%)	54/60 (90%)	160/180 (88.9%)
Blood	50	Within-run	56/60	57/60	56/60	169/180

	Ery/ μ L		(93.3%)	(95%)	(93.3%)	(93.9%)
		Between-run	57/60 (95%)	56/60 (93.3%)	55/60 (91.7%)	168/180 (93.3%)
Specific Gravity	1.010	Within-run	56/60 (93.3%)	56/60 (93.3%)	56/60 (93.3%)	168/180 (93.3%)
		Between-run	55/60 (91.7%)	55/60 (91.7%)	55/60 (91.7%)	165/180 (91.7%)
Leukocytes	25 Leu/ μ L	Within-run	58/60 (96.7%)	56/60 (93.3%)	57/60 (95%)	171/180 (95%)
		Between-run	56/60 (93.3%)	57/60 (95%)	56/60 (93.3%)	169/180 (93.9%)
Ascorbic Acid	20 mg/dL	Within-run	57/60 (95%)	56/60 (93.3%)	58/60 (96.7%)	171/180 (95%)
		Between-run	57/60 (95%)	58/60 (96.7%)	56/60 (93.3%)	171/180 (95%)

b. Linearity/assay reportable range:

The range of the device was assessed by repeat testing with spiked urine samples containing known concentrations for each analyte. Test material was adjusted to match the mid-point of a concentration range for a particular color block on the strip. The samples were repeated in replicates of 10 with three test strip lots and three operators (one lot per operator). The results are obtained by the direct comparison of the reagent strip with the color blocks on the bottle label. The results are presented in the tables below:

Urobilinogen	Intended Concentrations (mg/dL)				
Concentration reported (mg/dL)	1	2	4	8	12
12	0	0	0	1	30
8	0	0	1	28	0
4	0	2	28	1	0
2	1	28	1	0	0
1	27	0	0	0	0
0.1	2	0	0	0	0
% Agreement	90%	93.3%	93.3%	93.3%	100%

Glucose	Intended Concentrations (mg/dL)				
Concentration reported (mg/dL)	Negative	100	250	500	1000
1000	0	0	0	0	30
500	0	0	0	28	0

250	0	0	29	2	0
100	0	29	1	0	0
Negative	30	1	0	0	0
% Agreement	100%	96.7%	96.7%	93.3%	100%

Ketones	Intended Concentrations (mg/dL)				
Concentration reported (mg/dL)	Negative	5	15	40	80
80	0	0	0	1	29
40	0	0	0	29	1
15	0	2	29	0	0
5	1	28	1	0	0
Negative	29	0	0	0	0
% Agreement	96.7%	93.3%	96.7%	96.7%	96.7%

Bilirubin	Intended Concentrations (mg/dL)			
Concentration reported (mg/dL)	Negative	1	2	3
3	0	0	2	30
2	0	1	28	0
1	3	29	0	0
Negative	27	0	0	0
% Agreement	90%	96.7%	93.3%	100%

Protein	Intended Concentrations (mg/dL)					
Concentration reported (mg/dL)	Negative	15	30	100	300	1000
1000	0	0	0	0	0	29
300	0	0	0	0	30	1
100	0	0	0	28	0	0
30	0	2	29	2	0	0
15	2	28	1	0	0	0
Negative	28	0	0	0	0	0
% Agreement	93.3%	93.3%	96.7%	93.3%	100%	96.7%

Nitrite	Intended Concentrations (mg/dL)	
Concentration reported (mg/dL)	Negative	Positive
Positive	0	30
Negative	30	0
% Agreement	100%	100%

pH	Intended Concentrations					
Concentration reported (mg/dL)	5	6	6.5	7	8	9
9	0	0	0	0	0	30
8	0	0	0	0	29	0
7	0	0	3	29	1	0
6.5	0	0	27	1	0	0
6	0	28	0	0	0	0
5	30	2	0	0	0	0
% Agreement	100%	93.3%	90%	96.7%	96.7%	100%

Hemolyzed Blood	Intended Concentrations (Ery/ μ l)				
Concentration reported (Ery/ μ l)	Negative	7	25	50	250
250	0	0	0	0	30
50	0	0	0	29	0
25	0	0	30	1	0
7	0	29	0	0	0
Negative	30	1	0	0	0
% Agreement	100%	96.7%	100%	96.7%	100%

Non hemolyzed blood	Intended Concentrations (Ery/ μ l)		
Concentration reported (Ery/ μ l)	Negative	10	50
50	0	2	29
10	1	28	1
Negative	29	0	0
% Agreement	96.7%	93.3%	96.7%

Specific Gravity	Intended Concentrations g/mL						
Concentration reported (g/mL)	1.000	1.005	1.010	1.015	1.020	1.025	1.030
1.030	0	0	0	0	0	0	30
1.025	0	0	0	0	2	29	0
1.020	0	0	0	0	28	1	0
1.015	0	0	0	29	0	0	0
1.010	0	2	29	1	0	0	0
1.005	0	28	1	0	0	0	0
1.000	30	0	0	0	0	0	0
% Agreement	100%	93.3%	96.7%	96.7%	93.3%	96.7%	100%

Leukocytes	Intended Concentrations (Leu/ μ l)				
Concentration reported (Leu/ μ l)	Negative	5	18	75	500
500	0	0	0	0	30
75	0	0	0	29	0
18	0	1	28	1	0
5	2	27	2	0	0
Negative	28	2	0	0	0
% Agreement	93.3%	90%	93.3%	96.7%	100%

Ascorbic Acid	Intended Concentrations (mg/dL)			
Concentration reported (mg/dL)	Negative	10	20	40
40	0	0	0	29
20	0	1	30	1
10	0	29	0	0
Negative	30	0	0	0
% Agreement	100%	96.7%	100%	96.7%

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

No information on traceability was provided.

Real time stability studies have been conducted. Protocols and acceptance criteria were described and found to be acceptable. When stored at 2-30 °C the assay reagent is good until the expiration date 18 months.

d. Detection limit:

The sensitivity of the assay was validated by spiking negative/normal urine samples to known concentrations for each analyte (70% of the cut-off, 100% of the cut-off and 130% of the cut-off). The samples were repeated in replicates of 20 with three test strip lots and three operators (one lot per operator) in one day. The results are obtained by the direct comparison of the reagent strip with the color blocks on the bottle label. The results are presented in the tables below:

UROBILINOGEN			
Sample	70% Cut-off	100% Cut-off	130% Cut-off
Concentration	0.7 mg/dL	1 mg/dL	1.3 mg/dL
Negative Results	31	6	1
Positive Results	29	54	59
Percentage of positive	48.3%	90%	98.3%

GLUCOSE			
Sample	70% Cut-off	100% Cut-off	130% Cut-off
Concentration	70 mg/dL	100 mg/dL	130 mg/dL
Negative Results	18	2	0
Positive Results	42	58	60
Percentage of positive	70.0%	96.7%	100%

KETONES			
Sample	70% Cut-off	100% Cut-off	130% Cut-off
Concentration	3.5 mg/dL	5 mg/dL	6.5 mg/dL
Negative Results	14	1	1
Positive Results	46	59	59
Percentage of positive	76.7%	98.3%	98.3%

BILIRUBIN			
Sample	70% Cut-off	100% Cut-off	130% Cut-off
Concentration	0.35 mg/dL	0.5 mg/dL	0.65 mg/dL
Negative Results	12	2	0
Positive Results	48	58	60
Percentage of positive	80.0%	96.7%	100%

PROTEINS			
Sample	70% Cut-off	100% Cut-off	130% Cut-off
Concentration	10.5 mg/dL	15 mg/dL	19.5 mg/dL
Negative Results	20	1	1
Positive Results	40	59	59
Percentage of positive	66.7%	98.3%	98.3%

NITRITE			
Sample	70% Cut-off	100% Cut-off	130% Cut-off
Concentration	0.035 mg/dL	0.05 mg/dL	0.065 mg/dL
Negative Results	28	5	1
Positive Results	32	55	59
Percentage of positive	53.3%	91.7%	98.3%
HEMOGLOBIN			
Sample	70% Cut-off	100% Cut-off	130% Cut-off
Concentration	0.0105 mg/dL	0.015 mg/dL	0.0195 mg/dL
Negative Results	22	4	1
Positive Results	38	56	59
Percentage of positive	63.3%	93.3%	98.3%
NON HEMOLIZED ERYTHROCYTES			
Sample	70% Cut-off	100% Cut-off	130% Cut-off
Concentration	7 Ery/ μ L	10 Ery/ μ L	13 Ery/ μ L
Negative Results	19	1	0
Positive Results	41	59	60
Percentage of positive	68.3%	98.3%	100%
LEUKOCYTES			
Sample	70% Cut-off	100% Cut-off	130% Cut-off
Concentration	7 Leu/ μ L	10 Leu/ μ L	13 Leu/ μ L
Negative Results	24	3	0
Positive Results	36	57	60
Percentage of positive	60.0%	95.0%	100%
ASCORBIC ACID			
Sample	70% Cut-off	100% Cut-off	130% Cut-off
Concentration	7 mg/dL	10 mg/dL	13 mg/dL
Negative Results	22	1	0
Positive Results	38	59	60
Percentage of positive	63.3%	98.3%	100%

e. *Analytical specificity:*

Urine samples with known analyte concentration were spiked with possible interfering substances to various concentrations. The samples were repeated in replicates of 3. The results are obtained by the direct comparison of the reagent strip with the color blocks on the bottle label. The results are presented in the tables below:

Analyte	Interfering Substance	Impact on Test
Urobilinogen	p-Aminosalicylic Acid (≤ 500 mg/dL)	Do not interfere
	Nitrite (> 2.5 mg/dL)	False negative results
	Formol (> 0.2 mL/dL)	False negative results

Glucose	Specific Gravity (≥ 1.020)	Falsely decreased results
	pH > 8	Falsely decreased results
	Ascorbic Acid (≥ 25 mg/dL)	False negative results
	Ketones (> 40 mg/dL)	Falsely decreased results
Ketones	Specific Gravity (≤ 1.030)	Do not interfere
	pH (5 - 9)	Do not interfere
Bilirubin	Ascorbic Acid (≤ 100 mg/dL)	Do not interfere
	Light exposure (400 lux - ≥ 3 hours)	Falsely decreased results
Protein	Specific Gravity (≥ 1.020)	Falsely increased results
	pH (> 8)	Falsely increased results
Nitrite	Ascorbic Acid (≥ 50 mg/dL)	False negative results
	Specific Gravity (> 1.020)	Falsely decreased results
	pH (≥ 8)	Falsely decreased results
pH	Cross-contamination by adjacent reagent pads	Do not interfere
	Bacterial Contamination	Increasing Results
Blood	Ascorbic Acid (≥ 50 mg/dL)	False negative results
	Proteins (≥ 50 mg/dL)	False negative results
	Specific Gravity (≥ 1.020)	Falsely increased results
	pH (≥ 8)	Falsely decreased results
	Sodium Hypochlorite (≥ 300 ppm)	False positive results
Specific Gravity	Proteins (≥ 300 mg/dL)	Falsely increased results
	pH (≥ 8)	Falsely decreased results
	Glucose (≤ 4000 mg/dL)	Do not interfere
Leukocytes	Glucose (≥ 3000 mg/dL)	Falsely decreased results
	Proteins (≥ 500 mg/dL)	Falsely decreased results
	Formol (≥ 0.2 mL/dL)	False positive results
	Oxalic Acid (≥ 200 mg/dL)	Falsely decreased results
	Specific Gravity (≥ 1.025)	Falsely decreased results
	pH (≥ 8)	Falsely decreased results

f. Assay cut-off:

Not applicable for devices of this type. See detection limit section M.1.d above

2. Comparison studies:

a. Method comparison with predicate device:

Patient samples were tested in Point of Care settings by nine operators (three per site) on both the Wiener lab Urine strip and Bayer Multistix 10SG and the

Clinistrip URS 11 for the ascorbic acid. Additionally, some spiked samples were used to help cover the range of each analyte. The results are presented in the tables below:

Urobilinogen:

Bayer Multistix 10 SG	≥ 8 mg/dL	4 mg/dL	2 mg/dl	1 mg/dL	Normal
Weiner Lab Strip					
12 mg/dL	8	0	0	0	0
8	14	3	0	0	0
4	2	14	2	0	0
2	0	4	15	5	0
1	0	0	4	33	10
Normal	0	0	1	15	605
Total	24	21	22	53	615
% Agreement (Exactly Match)	91.6%	66.7%	68.2%	62.3%	98.4%
% Agreement (± 1 Color Block)	100%	100%	95.6%	100%	100%

Glucose:

Bayer Multistix 10 SG	≥2,000 mg/dL	1000 mg/dL	500 mg/dL	250 mg/dL	100 mg/dL	0 (Neg)
Weiner Lab Strip						
1,000 mg/dL	12	19	3	0	0	0
500	0	3	22	3	2	0
250	0	0	5	18	5	1
100	0	0	2	5	31	10
0 (Neg)	0	0	0	1**	18*	575
Total	12	22	32	27	56	586
% Agreement (Exactly Match)	100%	86%	69%	66.7%	55.4%	98.1%
% Agreement (±1 Color Block)	100%	100%	94%	96.3%	96.4%	99.8%

* 13 of the 18 negative results had other interferents present (5 with ascorbic acid > 24, 3 with ketones >40 and 5 with pH >8) that may affect glucose.

** pH >7.

Ketone:

Bayer Multistix 10 SG	80 mg/dL	40 mg/dl	15 mg/dL	5 mg/dL	0 (Neg)
Weiner Lab Strip					
80 mg/dL	40	5	0	0	0
40	2	29	6	1	0
15	0	3	31	13	2
5	0	1	1	45	6
0 (Neg)	0	0	2	13	535
Total	42	38	40	72	543
% Agreement (Exactly Match)	95.2%	76.3%	77.5%	62.5%	98.5%
% Agreement (±1 Color Block)	100%	97.4	95%	98.6%	99.6%

Bilirubin:

Bayer Multistix 10 SG	3 mg/dL (+++)	2 mg/dL (++)	1 mg/dL (+)	0 (Neg)
Weiner Lab Strip				
+++ 3 mg/dL	17	7	1	0
++ 2 mg/dL	4	24	6	0
+ 1 mg/dL	0	3	35	9
0 (Neg)	0	0	6	623
Total	21	34	48	632
% Agreement (Exactly Match)	80.1%	70.6%	72.9%	98.6%
% Agreement (±1 Color	100%	100%	97.9%	100%

Block)				
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Protein:

Bayer Multistix 10 SG	≥ 2000 mg/dL	300 mg/dL	100 mg/dL	30 mg/dL	15 mg/dL	0 (Neg)
Weiner Lab Strip						
1000 mg/dL	15	5	0	0	0	0
300	3	18	2	0	0	0
100	1	4	16	3	0	0
30	0	0	5	28	6	1
15	0	0	0	2	41	6
0 (Neg)	0	0	0	0	4	575
Total	19	27	23	33	51	582
% Agreement (Exactly Match)	78.9%	66.7%	69.6%	84.8%	80.4%	98.8%
% Agreement (± 1 Color Block)	94.7%	100%	100%	100%	100%	99.8%

Nitrite:

Bayer Multistix 10 SG	Positive	Negative
Weiner Lab Strip		
Positive	9	122
Negative	584	20
Total	593	142
% Agreement (Exactly Match)	93%	97%
% Agreement (± 1 Color Block)	100%	100%

pH:

Bayer Multistix 10 SG	8.5	8.0	7.5	7.0	6.5	6.0	5.0
Weiner Lab Strip							
9.0	112	5	2	0	0	0	0
8.0	11	108	9	2	0	0	0
7.0	0	6	11	89	8	3	0
6.5	0	0	0	5	109	2	1
6.0	0	0	0	0	5	115	9
5.0	0	0	0	0	1	10	112
Total	123	119	22	96	123	130	122
% Agreement	91.1%	90.8%	50%	92.7%	88.6%	88.5%	91.8%

(Exactly Match)							
% Agreement (± 1 Color Block)	100%	100%	90.9%	100%	99.2%	97.7%	99.2%

Blood:

Bayer Multistix 10 SG	200 ery/ μ L	80 ery/ μ L	25 ery/ μ L	10 ery/ μ L	0 (Neg)
Weiner Lab Strip					
250 ery/ μ L	39	2	1	0	0
50	3	51	5	0	0
25	0	5	47	7	0
10	0	0	12	60	9
0 (Neg)	0	0	0	3	491
Total	42	58	65	70	500
% Agreement (Exactly Match)	92.9%	87.9%	72.3%	85.7%	98.2%
% Agreement (± 1 Color Block)	100%	100%	98.5%	100%	100%

SG:

Bayer Multistix 10 SG	1.030	1.025	1.020	1.015	1.010	1.005	1.000
Weiner Lab Strip							
1.030	56	5	2	0	0	0	0
1.025	7	80	4	0	0	0	0
1.020	1	4	93	4	0	0	0
1.015	0	0	10	84	7	3	0
1.010	0	0	2	4	109	11	0
1.005	0	0	0	2	14	131	22
1000	0	0	0	0	0	12	68
Total	64	89	111	94	130	157	90
% Agreement (Exactly Match)	87.5%	89.9%	83.8%	89.4%	83.8%	83.4%	75.5%
% Agreement (± 1 Color Block)	98.4%	100%	96.4%	97.9%	100%	98.1%	100%

Leukocyte:

Bayer Multistix 10 SG	500 leu/ μ L	125 leu/ μ L	70 leu/ μ L	15 leu/ μ L	0 (Neg)
Weiner Lab Strip					
500 leu/ μ L	47	6	0	0	0
75	5	55	75	5	0

25	0	5	8	42	2
10	0	0	0	31	7
0 (Neg)	0	0	0	5	442
Total	52	66	83	83	451
% Agreement (Exactly Match)	90.4%	86%	90.4%	37%	98.0%
% Agreement (± 1 Color Block)	100%	100%	100%	94%	99.6%

Ascorbic Acid:

Teco Diagnostics Clinistrip	40 mg/dL	20 mg/dL	10 mg/dL	Negative
Weiner Lab Strip				
50 mg/dL	45	5	0	0
20	5	76	3	0
10	1	3	69	5
Negative	0	1	7	515
Total	51	85	79	520
% Agreement (Exactly Match)	88%	89%	87%	99%
% Agreement (± 1 Color Block)	98%	99%	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:

In the labeling the sponsor includes information about expected values from literature. References include the following:

Free, A.H. and Free, H.M. Urinalysis, clinical discipline of clinical science, CRC, Crit. Rev. Clin. Lab. Sc. 3/4: 481, 1972

Graff, L – A handbook of routine urinalysis, Philadelphia, J.B. Lippincott Co., 1983

Kark, R. et.al. – A primer of urinalysis, 2nd ed. N.Y., Harper and Row; 1963.

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.