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

A. 510(k) Number:

k051727

B. Purpose for Submission:

Clearance for urine reagent strips

C. Measurand:

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

D. Type of Test:

Qualitative Colorimetric Assay

E. Applicant:

Germaine Laboratories

F. Proprietary and Established Names:

AimStick Urine Reagent Strips

G. Regulatory Information:

1. Regulation section:

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 § 862.1550	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

2. Classification:

Class II: Urinary Glucose and Occult Blood
Class I: Urine Leukocytes, Urinary pH, Nitrite, Urinary Protein, Ketones, Urinary Urobilinogen, Urinary bilirubin and Specific Gravity

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

4. Panel:

75 Chemistry
81 Hematology

H. Intended Use:

1. Intended use(s):

See indications for use.

2. Indication(s) for use:

The AimStick Urine Reagent Strips are intended for the qualitative detection of Glucose, Bilirubin, Ketone, Specific gravity, Blood, pH, Protein, Urobilinogen, Nitrite, and Leukocytes in urine for persons to test by visual comparison with a color chart on the bottle label. This product is for professional use. Test results may provide information regarding the status of carbohydrate metabolism, kidney function, liver function, acid-base balance, and bacturia.

3. Special conditions for use statement(s):

For Prescription Use

4. Special instrument requirements:

Not applicable

I. Device Description:

The AimStick Urine Reagent Strips are plastic strips to which Glucose, Bilirubin, Ketone, Specific Gravity, Blood, pH, Protein, Urobilinogen, Nitrite, and Leukocytes reagent pads are affixed. The reagent pads react with the urine and provide a visible color reaction. The product is packaged with a drying agent in the bottle. Each strip is stable and ready to use.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Roche Chemstrip 10 SG (formerly Boehringer Mannheim)

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

   k896454

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended use	Used in determination of glucose, protein, pH, bilirubin, blood, ketone, urobilinogen, nitrite, specific gravity and leukocytes in urine	Same
Specimen	Urine	Same
Storage	15-30ºC	Same

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

None Referenced

L. Test Principle:

Glucose: The assay for glucose is based on the enzymatic glucose oxidase/peroxidase (GOD/POD) method. Glucose oxidase catalyzes the formation of gluconic acid and hydrogen peroxide from the oxidation of glucose. A second enzyme, peroxidase, catalyzes the reactions of hydrogen peroxidase with a potassium iodide chromogen to oxidize the chromogen to colors ranging from green to blue.

Bilirubin: The test is based on the coupling of bilirubin with diazotized

dichloroaniline in a strongly acid medium. The color produced on the reagent pad ranges through various shades of beige or tan.

Ketone: The test is based on the reaction between acetoacetate and sodium nitroprusside in an alkaline medium. A positive result produces a violet color.

Specific Gravity: The test is based on the release of protons in the presence of cations. The reaction produces hydrogenous ionogen, which reacts with a pH indicator that causes a color change.

Blood: This test is based on the peroxidase activity of hemoglobin and myoglobin creating a green color with oxidation of a chromogen. Intact erythrocytes which hemolyze on the test paper will produce a green dot.

pH: This test is based on the indicators methyl red and bromthymol blue that give a broad range of colors covering the entire urinary pH range.

Protein: The test is based on the protein-error-of-indicators principle. Anions in the specific pH indicator attracted by cations on protein molecules make the indicator further ionized, which changes its color. A positive reaction is indicated by a color change from yellow to light green to darker greens.

Urobilinogen: The test is based on the Ehrlich reaction in which p-diethylamino benzaldehyde in conjunction with a color enhancer reacts with urobilinogen in a strong acid medium. A positive reaction is indicated by a light pink to pink color.

Nitrite: The test is based on the conversion of nitrate to nitrite. The nitrate in the urine and aromatic amino sulphanilamide are diazotized to form a diazonium compound. The diazonium compound reacting with tetrahydro benzo(h) quinolin 3-phenol causes the color change. A positive reaction is indicated by a light pink to pink color.

Leukocytes: The test is based on the reaction of esterases, present in granulocytic leukocytes, which catalyze the hydrolysis of an indoxylcarbonic acid ester to indoxyl. A positive reaction is indicated by a light purple to dark purple color.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

   a. *Precision/Reproducibility:*

      Studies to assess the reproducibility of AimStick Urine Reagent Strips were conducted at several physician offices. One hundred and ninety six urine samples from patients were tested with the AimStick Urine Reagent Test Strips. The results were read visually and the data in exact agreement is presented in the tables below:

Glucose

Urine Values	Negative	100 mg/dL	250 mg/dL	500 mg/dL	1000 mg/dL
Results	182/182	8/8	4/4	1/1	1/1

Bilirubin

Urine Values	Neg	Small	Moderate
Results	164/170	19/21	4/5

Ketone

Urine Values	Negative	5 mg/dL	15 mg/dL	40 mg/dL	80 mg/dL
Results	152/153	31/33	7/8	0/1	1/1

Specific Gravity

Urine Values	1.000	1.005	1.010	1.015	1.020	1.025	1.030
Results	14/17	17/23	52/56	26/36	26/32	7/9	20/23

Blood

Urine Values	Neg	NH Trace	Trace	Small	Moderate	Large
Results	166/169	3/5	11/12	3/4	2/2	3/4

pH

Urine Values	5.0	6.0	6.5	7.0	7.5	8.0	8.5
Results	87/99	50/59	4/6	9/15	5/5	4/7	5/5

Protein

Urine Values	Neg	Trace	30 mg/dL	≥2000 mg/dL
Results	141/145	37/40	5/7	4/4

Urobilinogen

Urine Values	0.2 mg/dL	1.0 mg/dL
Results	141/145	7/8

Nitrite

Urine Values	Negative	Positive
Results	190/190	6/6

Leukocytes

Urine Values	Neg	Trace	Small	Moderate	Large
Results	163/164	14/18	2/3	5/7	4/4

b. *Linearity/assay reportable range:*

Not applicable

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

Stability studies are performed using two levels of commercially marketed urinalysis controls. The results of the study support the claim that the product is stable at room temperature for 18 months.

d. *Detection limit:*

The sponsor validates the sensitivity range of the AimStick Urine Reagent Strips by testing negative urine samples on a commercially available urine chemistry analyzer. Each urine sample is tested with three lot numbers of the AimStick Urine Reagent Strips. Each test is repeated 20 times with each lot number. The results of the studies supporting the sponsor's sensitivity claims are described below.

Glucose:
Negative urine samples are spiked with glucose at concentrations of 0, 50, 72 and 100 mg/dL. The results obtained from the study demonstrate a sensitivity of 50-100 mg/dL. The reagent pad does not react with lactose, galactose, or fructose.

Blood:
Negative urine samples are spiked with erythrocytes from venous blood. at concentrations of 0, 5, 10, 15 and 21 Cells/µL. The results obtained from the study demonstrate a sensitivity of 5-15 RBCs. (10 lysed RBCs is equivalent to 0.3 mg/dL of hemoglobin).

Bilirubin
Negative urine samples are spiked with bilirubin at concentrations of 0, 0.2, 0.3 and 0.5 mg/dL. The results obtained from the study demonstrate a sensitivity of 0.2-0.5 mg/dL.

Ketone:
Negative urine samples are spiked with acetoacetic acid at concentrations of 0, 5, 10, and 15 mg/dL. The results obtained from the study demonstrate a sensitivity of 5-10 mg/dL.

Protein
Negative urine samples are spiked with human albumin at concentrations of 0, 12, 15, 24 and 30 mg/dL. The results obtained from the study demonstrate a sensitivity of 15-30 mg/dL.

Urobilinogen:
Negative urine samples are spiked with urobilinogen at concentrations of 0, 0.2, 0.7, and 1.0 mg/dL. The results obtained from the study demonstrate a sensitivity of 0.2-1.0 mg/dL.

Nitrite:
Negative urine samples are spiked with nitrite at concentrations of 0, 0.09, 0.124, and 0.152 mg/dL. The results obtained from the study demonstrate a sensitivity of 0.09-0.52 mg/dL.

Leukocytes:
A urine sample with a high concentration of leukocytes is diluted with negative urine to produce three concentration levels-0, 5, 15, and 25 Cells/µL. The results obtained from the study demonstrate a sensitivity of 5-15 Cells/µL.

e. Analytical specificity:

Artificial urine is spiked with the following twenty seven possible interfering substances, one at a time. Each spiked urine sample is tested five times with the AimStick Urine Reagent Strips. None of the substances at the concentration tested interfered with the AimStick Urine Reagent Strips. The results are presented in the table below.

Interfering Substances	**Concentration**
Acetoacetate	250 mg/dL
Ammonium Chloride	200 mg/dL
Albumin[1]	1000 mg/dL
Ascorbic Acid	200 mg/dL
Bilirubin	3.2 mg/dL
Calcium Chloride	80 mg/dL
Citric Acid	65 mg/dL
Creatine	10 mg/dL
Creatinine	600 mg/dL
Glucose[2]	4100 mg/dL

Glycine	450 mg/dL
Hemoglobin[3]	5 mg/dL
KCL	1200 mg/dL
NaCl	1800 mg/dL
Oxalic Acid	70 mg/dL
Phenolphthalein	1200 mg/dL
Riboflavin	100 mg/dL
Sodium Acetate	20 mg/dL
Sodium Bicarbonate	1500 mg/dL
Sodium Nitrate	0.3 mg/dL
Sodium Nitrite	0.3 mg/dL
Sodium Phosphate	509 mg/dL
Theophylline	100 mg/dL
Urea	4000 mg/dL
Fructose	1.2 mg/dL
Galactose	0.5 mg/dL
Lactose	1.0 mg/dL

[1] Affected protein reagent only
[2] Affected glucose reagent only
[3] Affected blood reagent only

f. Assay cut-off:

Not Applicable

2. Comparison studies:

a. Method comparison with predicate device:

Studies were conducted at several physician offices. One hundred and ninety six urine samples from patients were tested with the AimStick Urine Reagent Test Strips and another commercially available product. The results were read visually and the data is presented in the table below:

AimStick Compared to Commercially Available Product-Both Read Visually

Analyte	Agreement Total	% Agreement within ± 1 color block	Analyte	Agreement Total	% Agreement within ± 1 color block
Glucose	195/196	100.00	pH	191/196	88.77
Bilirubin	187/196	99.48	Protein	187/196	100.00
Ketone	191/196	99.48	Urobilinogen	195/196	100.00
Specific Gravity	162/196	92.85	Nitrite	196/196	100.00
Blood	186/196	99.48	Leukocytes	188/196	99.48

Fifteen hundred ninety-nine random urine samples were read visually with the Aimstick Urine Reagent Test Strips and compared to commercially marketed strips run on a commercially marketed analyzer. The results of the new device were comparable to the currently marketed device. The results of the comparison study are presented in the table below:

Analyte	**Visual % Agreement ± 1 color block/1599 results**	**Analyzer % Agreement ± 1 color block /1599 results**
Glucose	98.0% /1567	97.8% /1564
Bilirubin	97.6% /1560	97.9% /1565
Ketone	98.3% /1572	97.9% /1565
Specific Gravity	97.5% /1559	96.9% /1549
Blood	96.8% /1548	97.1% /1553
pH	96.9% /1550	97.3% /1556
Protein	97.7% /1563	96.8% /1548
Urobilinogen	97.7%/1562	97.7%1563
Nitrite	97.2% /1554	97.4%/1558
Leukocytes	96.3% /1540	96.5%/1543

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):*

4. Clinical cut-off:

Not Applicable

5. Expected values/Reference Range

The following analytes should not be detectable using this device in the urine of healthy persons with this test: glucose, blood, ketones, protein, bilirubin,

nitrite, and leukocytes.

pH: First morning urine from healthy individuals will usually range from 5-6.

Specific gravity: Random urine values may vary from 1.001–1.035.

The normal range for Urobilinogen is 0.2 to 1.0 mg/dL.

These expected values are taken from the following references:

Schersten, B & Fritz, H: Subnormal Levels of Glucose in Urine. *JAMA* 201:129-132, 1967

Patterson, P et al.: Maternal and Fetal Ketone Concentrations in Plasma and Urine. *Lance*t: 862-865: April 22, 1967

Henry, JB, et al.: *Clinical Diagnosis and Measurement by Laboratory Methods*, 19th Edition, Philadelphia: WB Saunders: pp. 241-374, 454, 1996 (9)

Fraser, J et al.: Studies with a Simplified Nitroprusside Test for Ketone Bodies in Urine, Serum, Plasma and Milk. *Clinica Chemistry Acta II:* 372-378, 1965

A*birami, K, Tiwari, SC: Urinalysis in Clinical Practice*, Indian Academy of Clinical Medicine, Vol. 2, June 2001

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.