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

A. 510(k) Number:

k131600

B. Purpose for Submission:

New Device

C. Measurand:

Urine Glucose and Urine Protein

D. Type of Test:

Qualitative Urine Reagent Strip

E. Applicant:

Teco Diagnostics

F. Proprietary and Established Names:

URS-2GP (Glucose Protein) Urine Strips

G. Regulatory Information:

1. Regulation section:

   21 CFR 862.1340 Urinary Glucose (non-quantitative) test system

   21 CFR 862.1645 Urinary Protein or albumin (non-quantitative) test system

2. Classification:

   Class II
   Class I, meets the limitations of exemptions in 21 CFR 862.9 (c)(9)

3. Product code:

   JIL
   JIR

4. Panel:

   Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):

   See Indication(s) for use

2. Indication(s) for use:

   The URS-2GP (Glucose Protein) Urine Strips are visually read, semi-quantitative tests for the detection of glucose and protein in urine and are intended for prescription home use. Test results may provide information regarding the status of carbohydrate metabolism and kidney function.

3. Special conditions for use statement(s):

   For prescription home use

4. Special instrument requirements:

   None required; this is a single-use, visually read device.

I. Device Description:

This device is a reagent test strip which consists of glucose and protein reagent pads that are affixed onto firm plastic strips. The reagent pad areas are made of absorbent material saturated with chemically active substance, then dried and affixed to the plastic strip with double-sided adhesive. Each strip is packaged individually along with a desiccant in a sealed, foil pouch. A package insert is packaged along with the foil pouched into a box.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Teco Diagnostics Urine Reagent Strip-3 Parameter

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

   k940469

3. Comparison with predicate:

Similarities		
Item	Device Urine Glucose Protein Strip (k131600)	Predicate Urine Reagent Strip-3 Parameter (k940469)
Intended Use	Semi-quantitative determination of glucose and protein in urine	Same
Manufacturer	Teco Diagnostics	Same
Storage	15-30˚ C	Same
Test Time	Glucose (30 sec), Protein (1 min)	Same
Test Principle	Glucose: double sequential enzyme reaction using glucose oxidase and peroxidase. Protein: tetrabromophenol blue color reaction	Same

Differences		
Item	Device Urine Glucose Protein Strip (k131600)	Predicate Urine Reagent Strip-3 Parameter (k940469)
Measurands	glucose and protein in urine	glucose, protein, and pH in urine
Users	Lay users, Prescription home use	Prescription use
Size	108mm x 10mm strip, 10mm x 10mm pads.	80mm x 5mm strip, 5mm x 5 mm pads.
Packaging	Individual foil pouch.	Bottle of 100 strips
Sample Handling	Random urine (in-stream)	Random urine (dipped)

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

None referenced

L. Test Principle:

Glucose: The Urinary Glucose test is based on a double sequential enzyme reaction. One enzyme, glucose oxidase, catalyzes the formation of gluconic acid and hydrogen peroxide from the oxidation of glucose. A second enzyme, peroxidase, catalyzes the reaction of

hydrogen peroxide with potassium iodide chromogen causing the color to change from blue-green to greenish-brown.

Protein: The Urinary Protein test is based on the protein error-of-indicator principle. At a constant pH, the development of any green color is due to the presence of protein. Colors range from yellow for a negative reaction to yellow-green and blue-green for a positive reaction.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Within run precision studies were performed at three testing sites within the same day by three users by testing 20 replicates of three levels of one lot of urine controls using three lots of the device. Between-run precision studies were performed at three testing sites by 3 operators testing 3 levels of urine controls with 3 lots of the device by performing 4 replicate tests a day of 5 consecutive days for a total of 180 determinations. Visually read qualitative and semi-quantitative results were evaluated. The results are summarized in the table below.

Analyte Levels Tested

Analyte	Level 1 (mg/dL)	Level 2 (mg/dL)	Level 3 (mg/dL)
Glucose	0	100	500
Protein	0	30	300

Site 1

	Glucose		Protein	
Samples	Within-Run	Between-Run	Within-Run	Between-Run
Level 1	19/20	19/20	19/20	20/20
Level 2	20/20	20/20	19/20	18/20
Level 3	20/20	20/20	20/20	20/20
% Agreement (Exact match)	98% (59/60)	98% (59/60)	96% (58/60)	96% (58/60)
% Agreement (± 1 block)	100% (60/60)	100% (60/60)	100% (60/60)	100% (60/60)

Site 2

	Glucose		Protein	
Samples	Within-Run	Between-Run	Within-Run	Between-Run
Level 1	19/20	20/20	18/20	19/20
Level 2	19/20	20/20	18/20	18/20
Level 3	20/20	20/20	20/20	20/20
% Agreement (Exact match)	96% (58/60)	100% (60/60)	93% (56/60)	95% (57/60)
% Agreement (± 1 block)	100% (60/60)	100% (60/60)	100% (60/60)	100% (60/60)

Site 3

	Glucose		Protein	
Samples	Within-Run	Between-Run	Within-Run	Between-Run
Level 1	18/20	18/20	20/20	19/20
Level 2	19/20	18/20	20/20	19/20
Level 3	20/20	20/20	20/20	20/20
% Agreement (Exact match)	95% (57/60)	93% (56/60)	100% (60/60)	96% (58/60)
% Agreement (± 1 block)	100% (60/60)	100% (60/60)	100% (60/60)	100% (60/60)

Combined Data from Sites 1-3

	Glucose		Protein	
Samples	Within-Run	Between-Run	Within-Run	Between-Run
Level 1	56/60	57/60	57/60	58/60
Level 2	58/60	58/60	57/60	55/60
Level 3	60/60	60/60	60/60	60/60
% Agreement (Exact match)	96% (174/180)	97% (175/180)	96% (174/180)	96% (173/180)
% Agreement (± 1 block)	100% (180/180)	100% (180/180)	100% (180/180)	100% (180/180)

Precision at Concentrations near Cutoff Level

To determine the precision at concentrations near the cutoff levels, within run precision studies were performed at three testing sites within the same day by three users by testing 20 replicates of three levels of one lot of urine controls using three lots of the device. Between-run precision studies were performed at three testing sites by 3 users by testing 3 levels of urine controls with 3 lots of the device by performing 4 replicate tests a day on

5 consecutive days. Visually read qualitative and semi-quantitative results were evaluated. The results are summarized in the table below.

Analyte Levels Tested

Analyte	Level 1 (mg/dL)	Level 2 (mg/dL)	Level 3 (mg/dL)
Glucose	0	100	250
Protein	0	15	30

Site 1

	Glucose		Protein	
Samples	Within-Run	Between-Run	Within-Run	Between-Run
Level 1	20/20	20/20	20/20	20/20
Level 2	20/20	20/20	20/20	20/20
Level 3	20/20	20/20	20/20	20/20
% Agreement (Exact match)	100% (60/60)	100% (60/60)	100% (60/60)	100% (60/60)
% Agreement (± 1 block)	100% (60/60)	100% (60/60)	100% (60/60)	100% (60/60)

Site 2

	Glucose		Protein	
Samples	Within-Run	Between-Run	Within-Run	Between-Run
Level 1	20/20	20/20	20/20	20/20
Level 2	19/20	20/20	19/20	19/20
Level 3	19/20	20/20	18/20	19/20
% Agreement (Exact match)	96% (58/60)	100% (60/60)	95% (57/60)	96% (58/60)
% Agreement (± 1 block)	100% (60/60)	100% (60/60)	100% (60/60)	100% (60/60)

Site 3

	Glucose		Protein	
Samples	Within-Run	Between-Run	Within-Run	Between-Run
Level 1	20/20	20/20	20/20	20/20
Level 2	20/20	20/20	19/20	19/20
Level 3	20/20	20/20	18/20	19/20
% Agreement (Exact match)	100% (60/60)	100% (60/60)	95% (60/60)	96% (58/60)
% Agreement (± 1 block)	100% (60/60)	100% (60/60)	100% (60/60)	100% (60/60)

Combined Data from Sites 1-3

	Glucose		Protein	
Samples	Within-Run	Between-Run	Within-Run	Between-Run
Level 1	60/60	60/60	60/60	60/60
Level 2	59/60	60/60	58/60	58/60
Level 3	59/60	60/60	60/60	58/60
% Agreement (Exact match)	98% (178/180)	100% (180/180)	96% (174/180)	97% (176/180)
% Agreement (± 1 block)	100% (180/180)	100% (180/180)	100% (180/180)	100% (180/180)

b. Linearity/assay reportable range:

See (d) Detection limit for sensitivity studies across the range of test pad concentrations

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

Stability:

Shelf-life stability for the test strips was determined by accelerated testing. The accelerated test results support a shelf life of 24 months for sealed pouches stored at room temperature (15-30˚C). An ongoing real-time stability study is currently being performed to validate the shelf-life stability claims of the accelerated testing. Open-bottle stability is not applicable because the reagent strips are provided one strip per pouch and are intended to be used immediately after opening. The stability testing protocol and acceptance criteria were reviewed and found to be acceptable.

d. Detection limit:

To determine the sensitivity range of the glucose and protein color blocks, different concentrations of glucose and albumin were spiked into a negative urine sample to yield intermediate glucose and protein concentrations of 0 to 3000 mg/dL. Each of the concentrations was tested 20 times at one testing site by 3 users using 3 different lots of the device for a total of 180 readings. The sponsor defines sensitivity as the concentration where 95% of the test results yield the expected result. The results are summarized below:

Glucose sensitivity study

	% Sensitivity of Color Blocks					
Glucose (mg/dL)	Negative	100 (±)	250 (1+)	500 (2+)	1000 (3+)	>2000 (4+)
3000	0	0	0	0	0	100
2500	0	0	0	0	0	100
2000	0	0	0	0	0	100
1800	0	0	0	0	0	100
1500	0	0	0	0	0	100
1200	0	0	0	0	100	0
1000	0	0	0	0	100	0
900	0	0	0	0	100	0
750	0	0	0	100	0	0
600	0	0	0	100	0	0
500	0	0	0	100	0	0
450	0	0	0	100	0	0
375	0	0	78	22	0	0
300	0	0	100	0	0	0
250	0	0	100	0	0	0
225	0	0	78	0	0	0
150	0	22	0	0	0	0
125	0	100	0	0	0	0
100	0	100	0	0	0	0
75	33	67	0	0	0	0
50	100	0	0	0	0	0
25	100	0	0	0	0	0
0	100	0	0	0	0	0

Glucose Sensitivity Range

Color Block	Sensitivity Range
Negative	0-50 mg/dL
100 mg/dL	100-125 mg/dL
250 mg/dL	225-300 mg/dL
500 mg/dL	450-750 mg/dL
1000 mg/dL	900-1200 mg/dL
2000 mg/dL	1500-3000 mg/dL

Protein sensitivity study

	% Sensitivity of Color Blocks					
Protein (mg/dL)	Negative	15 (±)	30 (1+)	100 (2+)	300 (3+)	>2000 (4+)
3000	0	0	0	0	0	100
2500	0	0	0	0	0	100
2000	0	0	0	0	0	100
1500	0	0	0	0	0	100
1125	0	0	0	0	0	100
850	0	0	0	0	0	100
600	0	0	0	0	89	11
450	0	0	0	0	100	0
300	0	0	0	0	100	0
225	0	0	0	0	100	0
170	0	0	0	22	78	0
125	0	0	0	100	0	0
100	0	0	0	100	0	0
85	0	0	11	89	0	0
65	0	0	100	0	0	0
50	0	0	100	0	0	0
30	0	0	100	0	0	0
25	0	22	78	0	0	0
20	0	100	0	0	0	0
15	0	100	0	0	0	0
10	45	55	0	0	0	0
5	100	0	0	0	0	0
0	100	0	0	0	0	0

Protein sensitivity range

Color Block	Sensitivity Range
Negative	0-5 mg/dL
15 mg/dL	15-20 mg/dL
30 mg/dL	30-65mg/dL
100 mg/dL	100-125 mg/dL
300 mg/dL	225-450 mg/dL
2000 mg/dL	850-3000 mg/dL

e. Analytical specificity:

Cross Reactivity Studies

The device was tested with compounds similar to glucose and protein to assess cross reactivity with the measurands. Aliquots of urine samples containing 100 mg/dL and 500 mg/dL glucose were spiked with galactose, fructose, lactose, and sucrose to evaluate their cross reactivity with the determination of glucose in urine with the

device. Aliquots of urine samples containing 15 mg/dL and 100 mg/dL of protein were spiked with BSA, globulin, hemoglobin, Bence-Jones protein, and mucoprotein to evaluate their cross reactivity with the determination of protein in urine with the device. The study demonstrated that the urine glucose test did not react with any of the glucose analogues at concentrations up to 500 mg/dL. The urine protein test was specific for albumin, but also had some reactivity to globulin and Bence-Jones protein at concentrations higher than 100 mg/dL.

Cross reactivity study with glucose analogues

Glucose Analogue	Highest concentration tested at which no interference was observed.
Galactose	500 mg/dL
Fructose	500 mg/dL
Lactose	500 mg/dL
Sucrose	500 mg/dL

Cross reactivity study with protein analogues

Protein Analogue	Highest concentration tested at which no interference was observed.
BSA	100 mg/dL
Globulin	100 mg/dL
Bence-Jones	100 mg/dL
Hemoglobin	100 mg/dL
Mucoprotein	100 mg/dL

Interference Studies

The device was evaluated to assess the effects of potential interfering compounds on the measurands. Ketones, hemoglobin, ascorbic acid, bilirubin, MESNA, and sodium acetate were spiked into urine glucose aliquots containing 0, 100, 250, and 500 mg/dL of glucose and urine protein aliquots containing 0, 15, 30, and 100 mg/dL of protein to evaluate the interfering effects of these substances on protein and glucose determination by the device. Interference from urine specific gravity and urine pH were also assessed by testing glucose and protein in urine with a pH range of 5.0 to 9.0 and a specific gravity range of 1.000 to 1.030. The specimens were run in one day, at one testing site, by three operators using 3 different lots of the device. The protein and glucose results from the urine containing the potential interferents were compared to protein and glucose results from urine which did not contain the interfering substance. The sponsor defines interference as the concentration of a substance that causes the test reading to be incorrect by at least one color block. The interference study demonstrated that ascorbic acid at levels of 50 mg/dL had a false positive interference effect on the urine protein test; and MESNA at 25 mg/dL had a false positive interference effect on both the urine protein and urine glucose tests. In addition, hemoglobin at concentrations of $\geq$ 100 mg/dL resulted in an atypical color

on both the glucose and protein color pads.

The interference study demonstrated that there was no significant interference at the highest concentration tested for the determination of urine protein and urine glucose by the device for the following substances: bilirubin (5.0 mg/dL), ketone (80 mg/dL), and sodium acetate (45 mg/dL). In addition, the study demonstrated that a urine pH range of 5.0 to 9.0 and a urine specific gravity range of 1.000 to 1.0030 had no effect on the urine protein or urine glucose tests.

The sponsor states in the package insert labeling:

- Glucose test results may be lower if user is taking vitamin C or MESNA, commonly used in cancer chemotherapy.
- Protein test results may be lower if user is taking MESNA.
- User should not perform tests during menstrual period as high concentration of blood in urine could cause inaccurate results.
- Hemoglobin concentration of 100 mg/dL or above causes atypical color or urine which renders the urine glucose and urine protein tests invalid.

f. Assay cut-off:

Not applicable**.**

2. Comparison studies:

a. Method comparison with predicate device:

Accuracy of these test pads was previously evaluated and cleared under k940469.

b. Matrix comparison:

Not applicable, urine is the only matrix

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):

User Study

Lay user studies were conducted at three sites. Each site had 54 lay user participants. The participants performed the test on their own fresh urine (in-stream) using the candidate device according to the package insert labeling printed in English only. Aliquots of the participants' fresh urine were provided to healthcare professionals who performed comparison tests using the predicate device. For urine protein, 6 negative urine samples were spiked with albumin stock solution; and for urine glucose, 6 negative urine samples were spiked with glucose stock solution to obtain additional specimens in the >2000 mg/dL range. The spiked urine specimens were tested by 12 lay users and the results were compared to those obtained by professional testing. The comparison studies were performed in singlet, at random and were blinded. The method comparison results are summarized below.

Site 1 Glucose Test Results: Lay Users vs. Professional

Lay Users / Professional	Negative	100 mg/dL	250 mg/dL	500 mg/dL	1000 mg/dL	>2000 mg/dL
Negative	34	1				
100 mg/dL		8	2			
250 mg/dL			2			
500 mg/dL				2		
1000 mg/dL				1	3	
>2000 mg/dL						1
% Agreement Exact Match	92% (50/54)					
% Agreement ±1 Block	100% (54/54)					

Site 1 Protein Test Results: Lay Users vs. Professional

Lay Users / Professional	Negative	15 mg/dL	30 mg/dL	100 mg/dL	300 mg/dL	>2000 mg/dL
Negative	31	2				
15 mg/dL		7				
30 mg/dL			3	1		
100 mg/dL				3		
300 mg/dL				1	3	
>2000 mg/dL					1	2
% Agreement Exact Match	90% (49/54)					
% Agreement ±1 Block	100% (54/54)					

Site 2 Glucose Test Results: Lay Users vs. Professional

Lay Users / Professional	Negative	100 mg/dL	250 mg/dL	500 mg/dL	1000 mg/dL	>2000 mg/dL
Negative	30	2				
100 mg/dL		8	1			
250 mg/dL		1	4			
500 mg/dL				3	1	
1000 mg/dL					2	
>2000 mg/dL						2
% Agreement Exact Match	90% (49/54)					
% Agreement ±1 Block	100% (54/54)					

Site 2 Protein Test Results: Lay Users vs. Professional

Lay Users / Professional	Negative	15 mg/dL	30 mg/dL	100 mg/dL	300 mg/dL	>2000 mg/dL
Negative	28	2				
15 mg/dL		10				
30 mg/dL			3	1		
100 mg/dL				3		
300 mg/dL				1	2	
>2000 mg/dL						4
% Agreement Exact Match	92% (50/54)					
% Agreement ±1 Block	100% (54/54)					

Site 3 Glucose Test Results: Lay Users vs. Professional

Lay Users / Professional	Negative	100 mg/dL	250 mg/dL	500 mg/dL	1000 mg/dL	>2000 mg/dL
Negative	33	1				
100 mg/dL		7				
250 mg/dL			3			
500 mg/dL				2		
1000 mg/dL				1	2	
>2000 mg/dL					1	4
% Agreement Exact Match	94% (51/54)					
% Agreement ±1 Block	100% (54/54)					

Site 3 Protein Test Results: Lay Users vs. Professional

Lay Users / Professional	Negative	15 mg/dL	30 mg/dL	100 mg/dL	300 mg/dL	>2000 mg/dL
Negative	35	2				
15 mg/dL		8				
30 mg/dL			2	1		
100 mg/dL				3	1	
300 mg/dL					1	
>2000 mg/dL						1
% Agreement Exact Match	92% (50/54)					
% Agreement ±1 Block	100% (54/54)					

Combined Results sites 1-3 Glucose Test Results: Lay Users vs. Professional

Lay Users / Professional	Negative	100 mg/dL	250 mg/dL	500 mg/dL	1000 mg/dL	>2000 mg/dL
Negative	97	4				
100 mg/dL		23	3			
250 mg/dL		1	9			
500 mg/dL				7	1	
1000 mg/dL				2	7	
>2000 mg/dL					1	7
% Agreement Exact Match	92% (150/162)					
% Agreement ±1 Block	100% (162/162)					

Combined Results sites 1-3 Protein Test Results: Lay Users vs. Professional

Lay Users / Professional	Negative	15 mg/dL	30 mg/dL	100 mg/dL	300 mg/dL	>2000 mg/dL
Negative	94	6				
15 mg/dL		25				
30 mg/dL			8	3		
100 mg/dL				9	1	
300 mg/dL				1	7	
>2000 mg/dL					1	7
% Agreement Exact Match	92% (150/162)					
% Agreement ±1 Block	100% (162/162)					

Labeling Evaluation

A labeling evaluation was performed in conjunction with the lay user study. Study participants were asked to answer questionnaires to determine the usability of the test and the instructions given on the package insert. The readability of the package insert was assessed at 8.4 Flesch-Kincaid Grade Level. Results demonstrated that 98% of respondents found the package insert easy to understand, 85% found performing the test and reading the color chart not difficult, and 95% of respondents understood the meaning of the results of the tests.

4. Clinical cut-off**:**

Not applicable.

5. Expected values/Reference range:

The expected values are included in the labeling and are taken from literature references.

Urine Glucose: Small amounts of glucose are normally excreted by the kidney. Urine glucose concentrations up to 100 mg/dL are considered normal, but may be abnormal if found consistently. [1]

Urine Protein: Small amounts of protein may be excreted by the normal kidney. Urine protein concentrations up to 15 mg/dL are considered normal, but may be abnormal if found consistently.[2]

1. Schersten, B. and Fritz, H.: Subnormal Levels of Glucose in Urine. JAMA 201:129-132; (1967).

2. Burtis, C.A. and Ashwood, E.R.: Tietz Textbook of Clinical Chemistry 2nd Ed. 2205; (1994).

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.