

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

**A. 510(k) Number:**

k101673

**B. Purpose for Submission:**

Urinalysis Reader for use with previously cleared urinalysis strips (k970250)

**C. Measurand:**

Urine pH, leukocyte peroxidase, nitrite, protein, glucose, ketone, urobilinogen, bilirubin, blood, and specific gravity

**D. Type of Test:**

Semi-quantitative colorimetric assays

**E. Applicant:**

Teco Diagnostics

**F. Proprietary and Established Names:**

Uritek TC-101 Urine Analyzer  
Urine Reagent Strip (URS) 10

**G. Regulatory Information:**

Classification Name	Product Code	Device Class	Regulation Number
Urinary glucose (non-quantitative) test system	JIL	II	21 CFR§862.1340
Occult blood test	JIO	II	21 CFR§864.6550
Urinary urobilinogen (non-quantitative) test system	CDM	I	21 CFR§862.1785
Urinary bilirubin and its conjugates (non-quantitative) test system	JJB	I	21 CFR§862.1115
Ketones (non-quantitative test system)	JIN	I	21 CFR§862.1435

Classification Name	Product Code	Device Class	Regulation Number
Urinary protein or albumin (non-quantitative) test system	JIR	I	21 CFR§862.1645
Nitrite (non-quantitative) test system	JMT	I	21 CFR§862.1510
Leukocyte peroxidase test	LJX	I	21 CFR§864.7675
Urinary pH (non-quantitative) test system	CEN	I	21 CFR§862.1550
Specific Gravity	JRE	I	21 CFR§862.2800
Automated Urinalysis System	KQO	I	21 CFR§862.2900

Panel:

Chemistry (75), Hematology (81)

**H. Intended Use:**

1. Intended use(s):

Refer to indication(s) for use below.

2. Indication(s) for use:

The Uritek TC-101 urine analyzer is an automated, bench top instrument which is intended for prescription, in vitro diagnostic use only. The instrument is intended to be used together with the Urine Reagent Strips (URS) 10 as a system for the semi-quantitative detection of Glucose, Bilirubin, Ketone, Specific Gravity, Blood, pH, Protein, Urobilinogen, Nitrite and Leukocytes in urine. Test results may provide information regarding the status of carbohydrate metabolism, kidney and liver function, acid-base balance and bacteriuria.

3. Special conditions for use statement(s):

Prescription use only

4. Special instrument requirements:

Uritek TC-101 urine analyzer only

**I. Device Description:**

The Uritek TC-101 Urine Analyzer is a portable instrument which reads Teco Urine Reagent Strips (URS) 10 for testing in the clinical laboratory. The TC-101 can determine the intensity of

different colors on the reagent strip test area. This is done by irradiating the test area with light and detecting the reflectance of different wavelengths using an integrated sphere photo-detector. This photo-detector is filtered to measured wavelengths of 525nm, 550nm, 620nm, and 720nm by the integrated sphere. Results are calculated by a reflection rate which is a percentage of the total reflectance of the testing wavelength and are printed automatically.

The Uritek TC-101 reports semi-quantitative assay results for 10 urine analytes (glucose, bilirubin, ketone, specific gravity, blood, pH, protein, urobilinogen, nitrite, and leukocytes). Reagent strip results are automatically displayed on the screen in one minute. A printed hardcopy can also be created either from the results screen or recalled from memory. The analyzer features a display, internal printer, a serial computer interface and an electrical outlet. Communication between the operator and the analyzer is made through the display using the arrows and ‘yes’ or ‘no’ buttons on the front of the analyzer.

The Urine Reagent Strips (URS) 10 are urine test strips of which glucose, bilirubin, ketone, specific gravity, blood, pH, protein, urobilinogen, nitrite, and leukocyte reagent pad are affixed onto the firm plastic strips. The reagent pad areas are bibulous material saturated with chemically active substances, then dried and affixed to the plastic strip with double-sided adhesive.

**J. Substantial Equivalence Information:**

1. Predicate device name(s):

Bayer Clinitek Status with Bayer Multistix 10 SG Reagent Strips for Urinalysis

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

k031947

3. Comparison with predicate:

<b>Similarities</b>		
<b>Item</b>	<b>Device</b>	<b>Predicate (on Bayer Clinitek Status Analyzer)</b>
Intended Use	Same	For the detection of Glucose, Bilirubin, Ketone, Specific Gravity, Blood, pH, Protein, Urobilinogen, Nitrite and Leukocytes
User Entered Parameters	Same	Urine color and clarity, operator ID, and patient ID
Specimen	Same	Urine

<b>Differences</b>		
<b>Item</b>	<b>Device</b>	<b>Predicate (on Bayer Clinitek Status Analyzer)</b>
Calibration Method	Automatic; white reflective check strip	Dark and white reflective strip
Weight	5.21 lbs.	3.65 lbs.
Dimensions	6.4 (depth) x 8.5 (width) x 4.25 (height) inches	10.7 (depth) x 6.7 (width) x 6.2 (height) inches

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

1. ISO 14971:2007 Medical devices - Application of risk management to medical devices
2. CLSI EP9-A2 Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline Second edition (2002)
3. CLSI EP5-A2 Evaluation of Precision Performance of Clinical Chemistry Devices; Approved Guideline Second Edition
4. CLSI EP6-A: Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline
5. CLSI EP7-A2: Interference Testing in Clinical Chemistry, Approved Guideline- Second Edition (2005).

**L. Test Principle:**

Glucose: This test is based on a double sequential enzyme reaction. One enzyme, glucose oxidase, catalyzes the reaction in which glucose is oxidized to produce gluconic acid and hydrogen peroxide. A second enzyme, peroxidase, catalyzes the reaction of hydrogen peroxide with potassium iodide chromogen in which the chromogen is oxidized to different colors ranging from blue-green to greenish-brown through brown and dark brown.

Bilirubin: This test is based on the coupling of bilirubin with a diazotized dichloroaniline in a strongly acid medium. Varying bilirubin levels will produce light tan to reddish-brown color proportional to its concentration in urine.

Ketone: This test is based on the reaction of acetoacetic acid with sodium nitroprusside in a strongly basic medium. The colors range from beige or buff-pink color for a “Negative” reading to pink and pink-purple for a “Positive” reading.

Specific Gravity: This test is based on the apparent pKa change of certain pretreated polyelectrolytes in relation to the ionic concentration. In the presence of an indicator, the colors range from dark blue or blue-green in urine of low ionic concentration to green and yellow-green

in urine of higher ionic concentration.

Blood: This test is based on the pseudoperoxidase action of hemoglobin and erythrocytes which catalyzes the reaction of 3,3',5, 5'-tetramethyl-benzidine and buffered organic peroxide. The resulting colors range from orange to yellow-green and dark green. Very high blood concentration may cause the color development to continue to dark blue.

pH: This test is based on the well known double pH indicator method, where bromothymol blue and methyl red give distinguishable colors over the pH range of 5-9. The colors range from red-orange to yellow and yellow-green to blue-green.

Protein: This 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 green to blue-green for a "Positive" reaction.

Urobilinogen: This test is based on a modified Ehrlich reaction in which *p*-diethylaminobenzaldehyde reacts with urobilinogen in a strongly acid medium. Colors range from light pink to bright magenta.

Nitrite: This test depends on the conversion of nitrate to nitrite by the action of Gram-negative bacteria in the urine. The nitrite reacts with *p*-arsanilic acid to form a diazonium compound in an acid medium. The diazonium compound in turn couples with 1,2,3,4-tetrahydrobenzo(h)quinolin to produce a pink color.

Leukocytes: This test is based on the action of esterase present in leukocytes, which catalyzes the hydrolysis of an indoxyl ester derivative. The indoxyl ester liberated reacts with a diazonium salt to produce a beige-pink to purple color.

## **M. Performance Characteristics (if/when applicable):**

### 1. Analytical performance:

#### *a. Precision/Reproducibility:*

Precision was evaluated at three point of care (POC) sites. Three (3) operators per site did the testing on three (3) analyzers. A total of three (3) lots of URS-10 strips were used and three (3) levels of commercially available urine controls (at negative, low positive, and medium to high positive) were analyzed. At each site, the controls were analyzed in duplicate, twice a day for four (4) consecutive weeks (Monday through Friday) for a total of twenty (20) days of testing.

Results by site are shown below:

Site 1

Analyte	Control Expected Value	Measured Value (n)	Measured Value (n)	Measured Value (n)	Measured Value (n)	n
Glucose	Negative	Negative (80)	n/a	n/a	n/a	80
	Trace -500 mg/dL	100 (63)	250 (17)	n/a	n/a	80
	500 - $\geq$ 1000 mg/dL	n/a	500 (74)	$\geq$ 1000 (6)	n/a	80
Bilirubin	Negative	Negative (80)	n/a	n/a	n/a	80
	1+ -3+	n/a	2+ (11)	3+ (69)	n/a	80
	2+ -3+	n/a	n/a	3+ (80)	n/a	80
Ketones	Negative	Negative (80)	n/a	n/a	n/a	80
	Trace - 40 mg/dL	n/a	15 (10)	40 (70)	n/a	80
	40 - $\geq$ 80 mg/dL	n/a	40 (3)	80 (77)	n/a	80
Specific Gravity	$\leq$ 1.005 -1.015	$\leq$ 1.005 (2)	1.010 (68)	1.015 (10)	n/a	80
	$\leq$ 1.005 -1.015	n/a	1.010 (64)	1.015 (16)	n/a	80
	1.010- $\geq$ 1.030	1.010 (8)	1.015 (23)	1.020 (49)	n/a	80

Blood	Negative	Negative (80)	n/a	n/a	n/a	80
	Trace – 2+	n/a	1+ (20)	2+ (60)	n/a	80
	2+ - 3+	n/a	2+ (3)	3+ (77)	n/a	80
pH	$\geq$ 5.0 -6.5	5.0 (9)	6.0 (70)	6.5 (1)	n/a	80
	6.5 -8.5	6.5 (1)	7.0 (23)	7.5 (53)	8.0 (3)	80
	7.0-8.0	7.0 (27)	7.5 (53)	n/a	n/a	80

Protein	Negative	Negative (80)	n/a	n/a	n/a	80
	Negative -30 mg/dL	n/a	Trace (4)	30 (76)	n/a	80
	100 - $\geq$ 300 mg/dL	n/a	n/a	300 (80)	n/a	80
Urobilinogen	0.2 -1.0 EU/dL	0.2 (80)	n/a	n/a	n/a	80
	0.2 -1.0 EU/dL	0.2 (80)	n/a	n/a	n/a	80
	4.0 $\geq$ 8.0 EU/dL	n/a	n/a	8.0 (80)	n/a	80
Nitrite	Negative	Negative (80)	n/a	n/a	n/a	80
	Positive	n/a	Positive (80)	n/a	n/a	80
	Positive	n/a	Positive (80)	n/a	n/a	80
Leukocytes	Negative	Negative (80)	n/a	n/a	n/a	80
	Trace – 3+	1+ (74)	2+ (6)	n/a	n/a	80
	2+ - 3+	n/a	2+ (6)	3+ (74)	n/a	80

Site 2

Analyte	Control Expected Value	Measured Value (n)	Measured Value (n)	Measured Value (n)	n
Glucose	Negative	Negative (80)	n/a	n/a	80
	Trace -500 mg/dL	100 (80)	n/a	n/a	80
	500 - $\geq$ 1000 mg/dL	n/a	500 (80)	n/a	80
Bilirubin	Negative	Negative (80)	n/a	n/a	80
	1+ -3+	n/a	2+ (6)	3+ (74)	80
	2+ -3+	n/a	n/a	3+ (80)	80
Ketones	Negative	Negative (80)	n/a	n/a	80
	Trace - 40	n/a	n/a	40	80

Analyte	Control Expected Value	Measured Value (n)	Measured Value (n)	Measured Value (n)	n
	mg/dL			(80)	
	40 - $\geq$ 80 mg/dL	n/a	n/a	80 (80)	80
Specific Gravity	$\leq$ 1.005 -1.015	$\leq$ 1.005 (1)	1.010 (77)	1.015 (2)	80
	$\leq$ 1.005 -1.015	n/a	1.010 (77)	1.015 (3)	80
	1.010- $\geq$ 1.030	1.010 (9)	1.015 (46)	1.020 (25)	80
Blood	Negative	Negative (80)	n/a	n/a	80
	Trace - 2+	n/a	1+ (6)	2+ (74)	80
	2+ - 3+	n/a	2+ (1)	3+ (79)	80
pH	$\geq$ 5.0 -6.5	5.0 (65)	6.0 (15)	n/a	80
	6.5 -8.5	6.5 (1)	7.0 (35)	7.5 (44)	80
	7.0-8.0	7.0 (31)	7.5 (49)	n/a	80
Protein	Negative	Negative (80)	n/a	n/a	80
	Negative -30 mg/dL	n/a	n/a	30 (80)	80
	100 - $\geq$ 300 mg/dL	n/a	100 (0)	300 (80)	80

Urobilinogen	0.2 -1.0 EU/dL	0.2 (80)	n/a	n/a	80
	0.2 -1.0 EU/dL	0.2 (80)	n/a	n/a	80
	4.0 $\geq$ 8.0 EU/dL	n/a	n/a	8.0 (80)	80
Nitrite	Negative	Negative (80)	n/a	n/a	80
	Positive	n/a	Positive (80)	n/a	80
	Positive	n/a	Positive (80)	n/a	80
Leukocytes	Negative	Negative (80)	n/a	n/a	80
	Trace - 3+	1+	2+	n/a	80

		(72)	(8)		
	2+ - 3+	n/a	2+ (2)	3+ (78)	80

Site 3

Analyte	Control Expected Value	Measured Value (n)	Measured Value (n)	Measured Value (n)	n
Glucose	Negative	Negative (80)	n/a	n/a	80
	Trace -500 mg/dL	100 (77)	250 (3)	n/a	80
	500 - $\geq$ 1000 mg/dL	n/a	500 (80)	n/a	80
Bilirubin	Negative	Negative (80)	n/a	n/a	80
	1+ -3+	n/a	2+ (1)	3+ (79)	80
	2+ -3+	n/a	n/a	3+ (80)	80
Ketones	Negative	Negative (80)	n/a	n/a	80
	Trace - 40 mg/dL	n/a	n/a	40 (80)	80
	40 - $\geq$ 80 mg/dL	n/a	n/a	80 (80)	80
Specific Gravity	$\leq$ 1.005 -1.015	n/a	1.010 (77)	1.015 (3)	80
	$\leq$ 1.005 -1.015	n/a	1.010 (72)	1.015 (8)	80
	1.010- $\geq$ 1.030	n/a	1.015 (52)	1.020 (28)	80
Blood	Negative	Negative (80)	n/a	n/a	80
	Trace - 2+	n/a	1+ (3)	2+ (77)	80
	2+ - 3+	n/a	n/a	3+ (80)	80

pH	$\geq$ 5.0 -6.5	5.0 (56)	6.0 (24)	n/a	80
	6.5 -8.5	6.5	7.0	7.5	80

		(1)	(30)	(49)	
	7.0-8.0	7.0 (32)	7.5 (48)	n/a	80
Protein	Negative	Negative (80)	n/a	n/a	80
	Negative -30 mg/dL	n/a	n/a	30 (80)	80
	100 - ≥300 mg/dL	n/a	n/a	300 (80)	80
Urobilinogen	0.2 -1.0 EU/dL	0.2 (80)	n/a	n/a	80
	0.2 -1.0 EU/dL	0.2 (80)	n/a	n/a	80
	4.0 ≥8.0 EU/dL	n/a	n/a	8.0 (80)	80
Nitrite	Negative	Negative (80)	n/a	n/a	80
	Positive	n/a	Positive (80)	n/a	80
	Positive	n/a	Positive (80)	n/a	80
Leukocytes	Negative	Negative (80)	n/a	n/a	80
	Trace - 3+	1+ (67)	2+ (13)	n/a	80
	2+ - 3+	n/a	2+ (3)	3+ (77)	80

*b. Linearity/assay reportable range:*

The reportable range was evaluated in house using spiked samples to cover the reportable range of each of the ten parameters. Samples were prepared such that the expected concentrations corresponded to the color blocks for each assay. Fifteen (15) samples per concentration level were tested on three (3) analyzers with three (3) lots of URS-10. All results were an exact match to the expected concentration.

Analyte	Levels tested				
	Glucose	Neg	100	250	500
Bilirubin	Negative	0.5 mg/dL	1.0 mg/dL	3.0 mg/dL	n/a
Ketone	Negative	5	15	40	80

Analyte	Levels tested						
	Specific Gravity	1.005	1.010	1.015	1.020	1.025	1.030
Blood	Negative	Trace	0.05 mg/dL	0.125 mg/dL	0.25 mg/dL		
pH	5.0	6.0	6.5	7.0	7.5	8.0	8.5
Protein	Negative	15	30	100	300		
Urobilinogen	0.2	1.0	2.0	4.0	8.0		
Nitrite	Negative	Positive	n/a	n/a	n/a		
Leukocyte	Negative	15 cells/ $\mu$ L	70 cells/ $\mu$ L	125 cells/ $\mu$ L	500 cells/ $\mu$ L		

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

No traceability was provided. The strips were previously cleared under k970250.

d. *Detection limit:*

A Detection Limit study was performed in house to evaluate the minimum sensitivity level for each analyte on the URS-10 with the TC-101. Urine samples were spiked to known concentrations of each analyte, in the same manner as the linearity controls. These samples were then diluted to the lowest positive concentrations, or trace values, that are indicated on the Teco color chart. For each analyte, aliquots of the lowest positive concentrations were further diluted down to 75% (3:1) and 50% (1:1) with negative urine. The minimum sensitivity level for each analyte on the URS-10 is defined as the concentration level at which 50% of the results are positive for that concentration. Each sample was tested 15 times a day over 3 days, for a total of forty-five (45) results per sample. Three (3) lots of URS-10 were tested on three (3) analyzers with three (3) operators.

The sponsor identified the sensitivity level for each analyte as follows:

Glucose	75 mg/dL
Bilirubin	0.75 mg/dL
Ketone	5 mg/dL
Blood	10 cells/ uL
Protein	11.25 mg/dL
Urobilinogen	0.2 EU/dL
Nitrite	0.075 mg/dL
Leukocytes	11.25 cells/uL

pH Not applicable  
 Specific Gravity Not applicable

*e. Analytical specificity:*

Potential interferents in the table below were added to negative urine at the concentrations specified. Each urine sample was tested five (5) times with URS-10 strips. Results are presented in the tables below. All potential interferents are listed in the labeling.

Potential Interfering Substance	Conc. 1 (mg/dL)	Conc.1 (µmol/L)	Specificity Testing Results	Conc. 2 (mg/dL)	Conc.2 (µmol/L)	Specificity Testing Results
Acetoacetate	250	244.9	Trace for Ketone, Negative for all others	500	489.8	Trace for Ketone, Negative for all others
Ammonium Chloride	200	367.0	Negative for all	400	734.0	Negative for all
Albumin	1000	1.49	Positive for Protein, Negative for all others	2000	2.98	Positive for Protein, Negative for all others
Acetone	80	137.7	Negative for all	160	275.4	Negative for all
Beta-hydroxybutyric acid	80	76.84	Negative for all	160	153.7	Negative for all
Bilirubin	4	0.68	Positive for Bilirubin, Negative for all others	8	1.36	Positive for Bilirubin, Negative for all others
Calcium Chloride	80	72.08	Negative for all	160	144.2	Negative for all
Citric Acid	65	33.83	Negative for all	130	67.66	Elevated SG, all others Negative
Creatinine	600	530.4	Negative for all	1200	1060.8	Negative for all
Glucose	4000	2220.2	Positive for Glucose, Negative for	8000	4440.4	Positive for Glucose, Negative for all

			all others			others
Glycine	450	599.4	Negative for all	900	1198.8	Negative for all
Hemoglobin	1	0.002	Positive for Blood, Negative for all others	10	0.016	Positive for Blood, all others Negative
KCl	1200	1609.7	Elevated SG, all others Negative	2400	6438.8	Elevated SG, all others Negative
NaCl	1800	3079.9	Elevated SG, all others Negative	3600	6159.8	Elevated SG, all others Negative
Sodium Nitrate	0.3	0.03	Elevated SG, all others Negative	0.6	0.06	Negative for all
Sodium Nitrite	10	14.49	Positive for Nitrite, Negative for all others	30	43.47	Positive for Nitrite, Negative for all others
Sodium Phosphate	500	352.2	Elevated pH, Negative for all others	1000	704.4	Elevated pH, Negative for all others
Urea	4000	6660	Negative for all	8000	13320	Decreased specific gravity, all others Negative
Fructose	2	1.11	Negative for all	4	2.22	Negative for all
Galactose	0.5	0.28	Negative for all	1	0.56	Negative for all
Lactose	1	0.29	Negative for all	2	0.58	Negative for all
Sodium Bicarbonate	500	595.2	Elevated pH, Negative for all others	1000	1190.4	Elevated pH, Negative for all others

Riboflavin	2	0.531	Negative for all	8	2.124	Negative for all
Sulfa Compounds (Sulfamethoxazole)	16	6.3	Negative for all	32	12.6	Negative for all
Cephalosporins (Cefradine)	100	28.62	Negative for all	200	57.24	Negative for all
Phenolphthalein	2	0.62	Negative for all	4	1.24	Negative for all
Anti-Inflammatory Drugs (Ibuprofen)	4	1.92	Negative for all	8	7.68	Negative for all

In a different study, the following substances were analyzed at three or more concentrations and five replicates to evaluate potential interference with any of the assays. None of the substances listed below caused interference with any of the assays when tested at the concentrations listed:

Potential interferent	Concentrations tested
Amoxicillin	0, 50, and 100 mg/dL
Dexamethasone	0, 0.08, and 0.24 mg/dL
Excess Urine	n/a
Glucose (on pads other than glucose)	0, 500, and 1000 mg/dL
Ketone (on pads other than ketone)	0, 40, and 80 mg/dL
pH (on pads other than pH)	5.0, 6.0, 7.0, 7.5, 8.0, 8.5
Protein (on pads other than protein)	0, 100, and 300 mg/dL
Tetracycline	0, 20, and 40 mg/dL

For ascorbic acid, falsely decreased readings were obtained for bilirubin and nitrite at 30 mg/dL ascorbic acid. Other assays were not affected at 30 mg/dL ascorbic acid.

At higher concentrations of ascorbic acid, the following was observed:

- Glucose values were decreased starting at 60 mg/dL Ascorbic Acid
- Ketone values were decreased starting at 10,000 mg/dL Ascorbic Acid

- pH was decreased starting at 120 mg/dL Ascorbic Acid
- Protein was decreased starting at 3000 mg/dL Ascorbic Acid
- Urobilinogen was decreased starting at 2000 mg/dL Ascorbic Acid
- Leukocytes were decreased starting at 240 mg/dL Ascorbic Acid
- Specific Gravity was not affected at up to 480 mg/dL Ascorbic Acid

For specific gravity, no interference was seen for any of the assays from 1.005 to 1.030. When lower and higher specific gravities were tested, the following was observed:

- Protein was decreased at a specific gravity of 1.040
- Leukocytes were decreased at a specific gravity of 1.040

*f. Assay cut-off:*

Please see the Detection Limit section 1.d. above

2. Comparison studies:

*a. Method comparison with predicate device:*

The method comparison was performed at three (3) Point-of-Care (POC) Sites representing the intended users and intended use sites for this device. Three (3) operators at each site analyzed the samples.

In order to have sufficient amount of samples at the high positive levels for every analyte, spiked samples were included in the method comparison. Specifically, each POC site was provided with twenty (20) spiked urine samples to make up sixty (60) spiked urine samples in total. The spiked urine samples were kept frozen until testing. There were no significant differences in performance between sites.

Site 1

<b>Glucose</b>						
TC-101 Bayer Status	1000	500	250	100	0 (Neg)	Overall
1000	14	2				300
500	2	14	1			
250		1	14	1		
100			2	52		
0 (Neg)					197	
Total	16	17	17	53	197	
% Agreement (Exact Match)	87.5%	82.4%	82.4%	98.1%	100.0%	97.0%
% Agreement (+/- Color	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%

Block)						
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**Bilirubin**

TC-101 \ Bayer Status	3+	2+	1+	0 (Neg)	Overall
3+	23	2			300
2+	2	22	3		
1+		2	54	1	
0 (Neg)				191	
Total	25	26	57	192	
% Agreement (Exact Match)	92.0%	84.6%	94.7%	99.5%	96.7%
% Agreement (+/- Color Block)	100.0%	100.0%	100.0%	100.0%	100.0%

**Ketone**

TC-101 \ Bayer Status	80	40	15	Trace	0 (Neg)	Overall
80	14	2				300
40	2	15	2			
15		1	45	1		
Trace			2	28	3	
0 (Neg)					185	
Total	16	18	49	29	188	
% Agreement (Exact Match)	87.5%	83.3%	91.8%	96.6%	98.4%	95.7%
% Agreement (+/- Color Block)	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%

**Specific Gravity**

TC-101 \ Bayer Status	1.030	1.025	1.020	1.015	1.010	1.005	Overall
1.030	30						300
1.025	3	39	1				
1.020		3	55	1			
1.015				54	3		
1.010				2	64	5	
1.005						40	
Total	33	42	56	57	67	45	
% Agreement (Exact Match)	90.9%	92.9%	98.2%	94.7%	95.5%	88.9%	94.0%

% Agreement (+/- Color Block)	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
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### Blood

TC-101 Bayer Status	3+	2+	1+	Trace	0 (Neg)	Overall
3+	15	2				300
2+	3	20	1			
1+		1	27	1		
Trace			3	54	1	
0 (Neg)				1	171	
Total	18	23	31	56	172	
% Agreement (Exact Match)	83.3%	87.0%	87.1%	96.4%	99.4%	95.7%
% Agreement (+/- Color Block)	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%

### pH

TC-101 Bayer Status	8.5	8.0	7.5	7.0	6.5	6.0	≤5.5	Overall
8.5	22	2						300
8.0	6	19						
7.5		3	12	1				
7.0				93	2			
6.5					42	3		
6.0					2	60		
≤5.5							33	
Total	28	24	12	94	46	63	33	
% Agreement (Exact Match)	78.6%	79.2%	100.0%	98.9%	91.3%	95.2%	100.0%	93.7%
% Agreement (+/- Color Block)	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%

### Protein

TC-101 Bayer Status	300	100	30	Trace	0 (Neg)	Overall
300	16	1				300
100	2	16	2			
30		2	36	2		
Trace			2	35	2	
0 (Neg)				1	183	
Total	18	19	40	38	185	
% Agreement (Exact Match)	88.9%	84.2%	90.0%	92.1%	98.9%	95.3%

% Agreement (+/- Color Block)	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
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### Urobilinogen

TC-101 Bayer Status	8.0	4.0	2.0	1.0	0.2	Overall
8.0	11	1				300
4.0	1	18	1			
2.0			12	1		
1.0			1	40	1	
0.2				1	212	
Total	12	19	14	42	213	
% Agreement (Exact Match)	91.7%	94.7%	85.7%	95.2%	99.5%	97.7%
% Agreement (+/- Color Block)	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%

### Nitrite

TC-101 Bayer Status	Positive	Negative	Overall
Positive	38	1	300
Negative	1	260	
Total	39	261	
% Agreement (Exact Match)	97.4%	99.6%	99.3%
% Agreement (+/- Color Block)	100.0%	100.0%	

### Leukocyte

TC-101 Bayer Status	3+	2+	1+	Trace	0 (Neg)	Overall
3+	14	1				300
2+	1	15				
1+			37	3		
Trace			5	37	2	
0 (Neg)					185	
Total	15	16	42	40	187	
% Agreement (Exact Match)	93.3%	93.8%	88.1%	92.5%	98.9%	96.0%
% Agreement (+/- Color Block)	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%

Site 2

**Glucose**

TC-101 \ Bayer Status	1000	500	250	100	0 (Neg)	Overall
1000	14	2				300
500	2	14				
250		1	16	2		
100			1	48	1	
0 (Neg)					199	
Total	16	17	17	50	200	
% Agreement (Exact Match)	87.5%	82.4%	94.1%	96.0%	99.5%	97.0%
% Agreement (+/- Color Block)	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%

**Bilirubin**

TC-101 \ Bayer Status	3+	2+	1+	0 (Neg)	Overall
3+	23	3			300
2+	2	22			
1+		1	59	1	
0 (Neg)				189	
Total	25	26	59	190	
% Agreement (Exact Match)	92.0%	84.6%	100.0%	99.5%	97.7%
% Agreement (+/- Color Block)	100.0%	100.0%	100.0%	100.0%	100.0%

**Ketone**

TC-101 \ Bayer Status	80	40	15	Trace	0 (Neg)	Overall
80	14	2				300
40	2	14	1			
15		1	46	1		
Trace				36	2	
0 (Neg)					181	
Total	16	17	47	37	183	
% Agreement (Exact Match)	87.5%	82.4%	97.9%	97.3%	98.9%	97.0%
% Agreement (+/- Color Block)	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%

**Specific Gravity**

TC-101 Bayer Status	1.030	1.025	1.020	1.015	1.010	1.005	Overall
1.030	22						300
1.025	2	25	2				
1.020		2	80	3			
1.015			1	49	5		
1.010				3	56	3	
1.005					2	45	
Total	24	27	83	55	63	48	
% Agreement (Exact Match)	91.7%	92.6%	96.4%	89.1%	88.9%	93.8%	92.3%
% Agreement (+/- Color Block)	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%

### Blood

TC-101 Bayer Status	3+	2+	1+	Trace	0 (Neg)	Overall
3+	15	2				300
2+	2	19	2			
1+		2	30	2		
Trace			3	46	1	
0 (Neg)					176	
Total	17	23	35	48	177	
% Agreement (Exact Match)	88.2%	82.6%	85.7%	95.8%	99.4%	95.3%
% Agreement (+/- Color Block)	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%

### pH

TC-101 Bayer Status	8.5	8.0	7.5	7.0	6.5	6.0	≤5.5	Overall
8.5	21	2						300
8.0	4	19						
7.5			21	2				
7.0			2	77				
6.5				1	50	3		
6.0					3	66		
≤5.5						2	27	
Total	25	21	23	80	53	71	27	
% Agreement (Exact Match)	84.0%	90.5%	91.3%	96.3%	94.3%	93.0%	100.0%	93.7%
% Agreement (+/- Color Block)	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%

**Protein**

TC-101 \ Bayer Status	300	100	30	Trace	0 (Neg)	Overall
300	14	1				300
100	1	17	1			
30			36	4		
Trace			1	36	1	
0 (Neg)					188	
Total	15	18	38	40	189	
% Agreement (Exact Match)	93.3%	94.4%	94.7%	90.0%	99.5%	97.0%
% Agreement (+/- Color Block)	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%

**Urobilinogen**

TC-101 \ Bayer Status	8.0	4.0	2.0	1.0	0.2	Overall
8.0	12	1				300
4.0	1	14	1			
2.0			13	1		
1.0				28		
0.2				1	228	
Total	13	15	14	30	228	
% Agreement (Exact Match)	92.3%	93.3%	92.9%	93.3%	100.0%	98.3%
% Agreement (+/- Color Block)	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%

**Nitrite**

TC-101 \ Bayer Status	Positive	Negative	Overall
Positive	35	2	300
Negative		263	
Total	35	265	
% Agreement (Exact Match)	100.0%	99.2%	99.3%
% Agreement (+/- Color Block)	100.0%	100.0%	

**Leukocyte**

TC-101 Bayer Status	3+	2+	1+	Trace	0 (Neg)	Overall
3+	15	2				300
2+	1	14				
1+		1	33	4		
Trace			1	38	2	
0 (Neg)					189	
Total	16	17	34	42	191	
% Agreement (Exact Match)	93.8%	82.4%	97.1%	90.5%	99.0%	96.3%
% Agreement (+/- Color Block)	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%

Site 3

**Glucose**

TC-101 Bayer Status	1000	500	250	100	0 (Neg)	Overall
1000	14	2				304
500	2	14	2			
250		1	15	1		
100				53	1	
0 (Neg)					199	
Total	16	17	17	54	200	
% Agreement (Exact Match)	87.5%	82.4%	88.2%	98.1%	99.5%	97.0%
% Agreement (+/- Color Block)	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%

**Bilirubin**

TC-101 Bayer Status	3+	2+	1+	0 (Neg)	Overall
3+	24				304
2+	2	22	2		
1+		3	52	2	
0 (Neg)			1	196	
Total	26	25	55	198	
% Agreement (Exact Match)	92.3%	88.0%	94.5%	99.0%	96.7%
% Agreement (+/- Color Block)	100.0%	100.0%	100.0%	100.0%	100.0%

**Ketone**

TC-101 Bayer Status	80	40	15	Trace	0 (Neg)	Overall
80	15	1				304
40	1	16	1			
15			54	2		
Trace			3	30	1	
0 (Neg)				2	178	
Total	16	17	58	34	179	
% Agreement (Exact Match)	93.8%	94.1%	93.1%	88.2%	99.4%	96.4%
% Agreement (+/- Color Block)	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%

**Specific Gravity**

TC-101 Bayer Status	1.030	1.025	1.020	1.015	1.010	1.005	Overall
1.030	19	2					304
1.025		3	2				
1.020		1	45	3			
1.015			3	70	3		
1.010				3	90	3	
1.005					2	55	
Total	19	6	50	76	95	58	
% Agreement (Exact Match)	100.0%	50.0%	90.0%	92.1%	94.7%	94.8%	92.8%
% Agreement (+/- Color Block)	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%

**Blood**

TC-101 Bayer Status	3+	2+	1+	Trace	0 (Neg)	Overall
3+	16					304
2+		24	3			
1+		3	29	1		
Trace			2	39	3	
0 (Neg)					184	
Total	16	27	34	40	187	
% Agreement (Exact Match)	100.0%	88.9%	85.3%	97.5%	98.4%	96.1%
% Agreement (+/- Color Block)	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%

**pH**

TC-101 Bayer Status	8.5	8.0	7.5	7.0	6.5	6.0	≤5.5	Overall
8.5	28	2						304
8.0	2	25						
7.5		1	19	2				
7.0			2	96	1			
6.5				2	47	1		
6.0					2	53	2	
≤5.5						1	18	
Total	30	28	21	100	50	55	20	
% Agreement (Exact Match)	93.3%	89.3%	90.5%	96.0%	94.0%	96.4%	90.0%	94.1%
% Agreement (+/- Color Block)	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%

**Protein**

TC-101 Bayer Status	300	100	30	Trace	0 (Neg)	Overall
300	16					304
100	1	17	4			
30		1	38	1		
Trace				35	2	
0 (Neg)					189	
Total	17	18	42	36	191	
% Agreement (Exact Match)	94.1%	94.4%	90.5%	97.2%	99.0%	97.0%
% Agreement (+/- Color Block)	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%

**Urobilinogen**

TC-101 Bayer Status	8.0	4.0	2.0	1.0	0.2	Overall
8.0	13	1				304
4.0		16				
2.0			12	1		
1.0			1	47	3	
0.2				2	208	
Total	13	17	13	50	211	
% Agreement (Exact Match)	100.0%	94.1%	92.3%	94.0%	98.6%	97.4%
% Agreement (+/- Color Block)	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%

**Nitrite**

TC-101 \ Bayer Status	Positive	Negative	Overall
Positive	56	1	304
Negative		247	
Total	56	248	
% Agreement (Exact Match)	100.0%	100.0%	99.7%
% Agreement (+/- Color Block)	100.0%	100.0%	

**Leukocyte**

TC-101 \ Bayer Status	3+	2+	1+	Trace	0 (Neg)	Overall
3+	18	1				304
2+	1	11				
1+		3	43	1		
Trace			3	39	1	
0 (Neg)				1	182	
Total	19	15	46	41	183	
% Agreement (Exact Match)	94.7%	73.3%	93.5%	95.1%	99.5%	96.4%
% Agreement (+/- Color Block)	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%

*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):*

Not applicable.

4. Clinical cut-off:

Not applicable.

5. Expected values/Reference range:

Glucose:	Negative
Bilirubin:	Negative
Ketones:	Negative
Specific Gravity:	1.002 – 1.030 (random)
Blood:	Negative
pH:	4.5 – 8.0
Protein:	Negative
Urobilinogen:	0.2 – 1.0 Ehrlich Units/dL
Nitrite:	Negative

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**N. Instrument Name:**

Uritek TC-101 Urine Analyzer

**O. System Descriptions:**

1. Modes of Operation:

Single or 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:

A patient ID can be input manually at the time of analysis

4. Specimen Sampling and Handling:

Single or continuous testing mode. Users must manually dip the urine reagent strip into the urine sample, blot the strip lengthwise, and place the strip on the strip bed.

5. Calibration:

The Uritek TC-101 does not require daily calibration, as the instrument performs a system calibration each time it is turned on. The white check strips included with the analyzer provides the user the ability to check the performance of the analyzer compared to a set standard.

6. Quality Control:

The package insert reads as follows: Quality control should be performed on the reagent strips by testing known negative and positive commercially available controls. Two levels of controls need to be analyzed after performing maintenance or service on the TC-101, with each new shipment, each new lot, whenever a new bottle of test strips is first opened, and every thirty days to check storage conditions. Water should not be used as a negative control. Each laboratory should establish its own goals for adequate standards of performance, and should perform quality control if there is a question about the performance of the strips or the specimen handling. It is recommended that users 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:**

None

**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.