

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

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

k160372

**B. Purpose for Submission:**

New urinalysis test system composed of a previously cleared urinalysis analyzer (k152835) and previously cleared urinalysis strips (k970250)

**C. Measurand:**

Urinary glucose, blood, leukocytes, pH, nitrite, protein, ketones, urobilinogen, bilirubin, and specific gravity

**D. Type of Test:**

Qualitative and semi-quantitative urinalysis

**E. Applicant:**

Teco Diagnostics

**F. Proprietary and Established Names:**

Uritek TC-201 Urine Chemistry Test System  
Uritek TC-201 Urine Analyzer  
Uritek Reagent Strips (URS-10)

**G. Regulatory Information:**

Regulation	Product Code	Test Name	Device Class	Panel
21 CFR 862.1340	JIL	Urinary Glucose (nonquantitative) Test System	II	Chemistry (75)
21 CFR 864.6550	JIO	Occult Blood Test	II	Hematology (81)
21 CFR 862.2900	KQO	Automated Urinalysis System	I	Chemistry (75)
21 CFR 864.7675	LJX	Leukocyte Peroxidase Test	I	Hematology (81)
21 CFR 862.2800	JRE	Refractometer for clinical use	I	Chemistry (75)
21 CFR 862.1550	CEN	Urinary pH (nonquantitative)	I	Chemistry (75)

Regulation	Product Code	Test Name	Device Class	Panel
		Test System		
21 CFR 862.1510	JMT	Nitrite (nonquantitative) Test System	I	Chemistry (75)
21 CFR 862.1645	JIR	Urinary Protein or Albumin (nonquantitative) Test System	I	Chemistry (75)
21 CFR 862.1435	JIN	Ketones (nonquantitative) Test System	I	Chemistry (75)
21 CFR 862.1785	CDM	Urinary Urobilinogen (nonquantitative) Test System	I	Chemistry (75)
21 CFR 862.1115	JJB	Urinary Bilirubin and its conjugates (nonquantitative) Test System	I	Chemistry (75)

#### H. Intended Use:

1. Intended use(s):

See Indication(s) for use below.

2. Indication(s) for use:

The Uritek TC-201 Urine Chemistry Test System consists of the Uritek TC-201 Urine Chemistry Analyzer and the Teco Diagnostics Urine Reagent (URS-10) Strips. The Uritek TC-201 Urine Analyzer is an automated, bench top instrument which is intended for point-of-care, in vitro diagnostic use only. The instrument is intended to be used together with the Teco Diagnostics Urine Reagent (URS-10) Strips as a system for semi-quantitative detection of Glucose, Bilirubin, Ketone, Specific Gravity, Blood, pH, Protein, Urobilinogen, Nitrite and Leukocytes in urine. These measurements are used to aid in the diagnosis of metabolic disorders, kidney function anomalies, urinary tract infections and liver function.

3. Special conditions for use statement(s):

For prescription use

4. Special instrument requirements:

Uritek TC-201 Urine Analyzer

#### I. Device Description:

The Uritek TC-201 Urine Analyzer (TC-201) is a portable instrument for use with Urine Reagent (URS-10) Strips for testing at point-of-care sites. The analyzer can determine the intensity of different colors on the reagent strip test area using the principle of light reflection

by photodiode. 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-201 Urine Analyzer reports semi-quantitative results for Glucose, Bilirubin, Ketone, Specific Gravity, Blood, pH, Protein, Urobilinogen, Nitrite, and Leukocytes in urine. 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 user interface touch screen on the front surface of the instrument. 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 Teco Diagnostic Urine Reagent Strips (URS-10, previously cleared in k970250) are firm plastic strips to which ten different reagent pads are affixed. The reagent pad areas are bibulous material saturated with chemically active substances, then dried and affixed to the plastic strip with double-sided adhesive. The Urine Reagent (URS-10) Strips provide tests for the semi-quantitative and qualitative determination of Glucose, Bilirubin, Ketone, Specific Gravity, Blood, pH, Protein, Urobilinogen, Nitrite, and Leukocytes in urine.

**J. Substantial Equivalence Information:**

1. Predicate device name(s):

Siemens Clinitek Status Plus Analyzer

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

k091216

3. Comparison with predicate:

<b>Similarities</b>		
<b>Item</b>	<b>Candidate Device Uritek TC-201 Test System</b>	<b>Predicate Device Clinitek Status Plus k091216</b>
<b>Intended Use</b>	For the semi-quantitative detection of glucose, bilirubin, ketone, specific gravity, blood, pH, protein, urobilinogen, nitrite, and leukocytes in urine.	Same
<b>Indications for Use</b>	Aid in the diagnosis of metabolic disorders, kidney function anomalies, urinary tract infections, and liver function.	Same
<b>Analyzer Basic Operating Principle</b>	Reflectance Photometer	Same

<b>Similarities</b>		
<b>Item</b>	<b>Candidate Device Uritek TC-201 Test System</b>	<b>Predicate Device Clinitek Status Plus k091216</b>
Specimen Type	Urine	Same
Analyzer calibration method	Self-calibration with a white reflective check area located at the back of the test strip bed	Same
Analyzer operating conditions	64-86°F (18-30°C); 18%-80% R.H.	Same
Test Strip physical description	Plastic strips affixed with reagent pads	Same
Test strip storage temperature	59-86°F (15-30°C)	Same

<b>Differences</b>		
<b>Item</b>	<b>Candidate Device Uritek TC-201 Test System</b>	<b>Predicate Device Clinitek Status Plus k091216</b>
Analyzer Power	Input 100-240 VAC ± 20% and 45-65Hz, output + 9V	Input 100-240 VAC ± 20% and 45-65Hz, output + 9V or 6 AA non-rechargeable alkaline batteries
Analyzer Memory	Stores up to 2000 test results	Stores up to 950 test results
Display Language	English, Spanish, Chinese	English, Spanish
Screen Display	Color	Mono-tone
Analyzer Dimensions	Width 7.25 inches Depth 10.5 inches Height 6.5 inches	Width 6.7 inches Depth 10.7 inches Height 6.2 inches
Analyzer Weight	4.14 lbs (1.88 kg)	3.65 lbs (1.66 kg)
Test Strips	Teco Diagnostic Urine Reagent (URS-10) strips	Clinitek Multistix 10 SG

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

ISO 14971 “Medical Devices – Applications to risk management to medical devices”

EP07-A2 “Interference Testing in Clinical Chemistry; Approved Guideline – Second Edition”

**L. Test Principle:**

Analyte	Test Principle
Glucose	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	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	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	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	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	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	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	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

Analyte	Test Principle
	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.
Leukocyte	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:*

Within Run Precision of the Uritek TC-201 Urine Chemistry Test System was evaluated by three operators testing 20 replicates of commercially available urine control solutions at (negative, low positive, and high positive) on three analyzers with three strip lots.

The results are summarized below:

**Control Level I (High analyte concentration)**

Analyte	Control Level I	Exact Match Agreement (%)	+/- 1 Color Block Agreement (%)
Glucose	1000 mg/dL	177/180 (98.33%)	180/180 (100%)
Bilirubin	Large	177/180 (98.33%)	180/180 (100%)
Ketone	80 mg/dL	179/180 (99.44%)	180/180 (100%)
Specific Gravity	1.015	176/180 (97.78%)	180/180 (100%)
Blood	Large	180/180 (100%)	180/180 (100%)
Nitrite	Positive	180/180 (100%)	180/180 (100%)
Protein	300 mg/dL	180/180 (100%)	180/180 (100%)
Urobilinogen	8.0 EU/dL	180/180 (100%)	180/180 (100%)
Leukocyte	Large	180/180 (100%)	180/180 (100%)
pH	8.0	173/180 (96.11%)	180/180 (100%)

**Control Level II (Low analyte concentration)**

Analyte	Control Level II	Exact Match Agreement (%)	+/- 1 Color Block Agreement (%)
Glucose	250 mg/dL	179/180 (99.44%)	180/180 (100%)
Bilirubin	Small	180/180 (100%)	180/180 (100%)
Ketone	40 mg/dL	180/180 (100%)	180/180 (100%)
Specific Gravity	1.010	178/180 (98.89%)	180/180 (100%)
Blood	Moderate	180/180 (100%)	180/180 (100%)
Nitrite	Positive	180/180 (100%)	180/180 (100%)
Protein	Trace	179/180 (99.44%)	180/180 (100%)
Urobilinogen	0.2 EU/dL	180/180 (100%)	180/180 (100%)
Leukocyte	Moderate	178/180 (98.89%)	180/180 (100%)
pH	8.0	179/180 (99.44%)	180/180 (100%)

**Control Level III (Negative)**

Analyte	Control Level III	Exact Match Agreement (%)	+/- 1 Color Block Agreement (%)
Glucose	Negative	180/180 (100%)	180/180 (100%)
Bilirubin	Negative	180/180 (100%)	180/180 (100%)
Ketone	Negative	180/180 (100%)	180/180 (100%)
Specific Gravity	1.010	179/180 (99.44%)	180/180 (100%)
Blood	Negative	180/180 (100%)	180/180 (100%)
Nitrite	Negative	180/180 (100%)	180/180 (100%)
Protein	Negative	180/180 (100%)	180/180 (100%)
Urobilinogen	0.2 EU/dL	180/180 (100%)	180/180 (100%)
Leukocyte	Negative	180/180 (100%)	180/180 (100%)
pH	6.0	178/180 (98.89%)	180/180 (100%)

The Run to Run precision was performed by testing three replicates of three levels of control solution (negative, low positive, and high positive) by two operators on two analyzers with three lots of URS-10 strips over two non-consecutive runs per day for 10 days. Run 1 and Run 2 were separated by at least 1 hour.

The results are summarized below:

**Control Level I (High analyte concentration)**

Analyte	Control Level I	Exact Match Agreement (%)	+/- 1 Color Block Agreement (%)
Glucose	1000 mg/dL	120/120 (100%)	120/120 (100%)
Bilirubin	Large	119/120 (99.17%)	120/120 (100%)
Ketone	80 mg/dL	120/120 (100%)	120/120 (100%)
Specific Gravity	1.015	118/120 (98.33%)	120/120 (100%)
Blood	Large	120/120 (100%)	120/120 (100%)
Nitrite	Positive	120/120 (100%)	120/120 (100%)
Protein	300 mg/dL	120/120 (100%)	120/120 (100%)
Urobilinogen	8.0 EU/dL	120/120 (100%)	120/120 (100%)
Leukocyte	Large	120/120 (100%)	120/120 (100%)
pH	8.0	117/120 (97.50%)	120/120 (100%)

**Control Level II (Low analyte concentration)**

Analyte	Control Level II	Exact Match Agreement (%)	+/- 1 Color Block Agreement (%)
Glucose	250 mg/dL	120/120 (100%)	120/120 (100%)
Bilirubin	Small	120/120 (100%)	120/120 (100%)
Ketone	40 mg/dL	120/120 (100%)	120/120 (100%)
Specific Gravity	1.010	117/120 (97.50%)	120/120 (100%)
Blood	Moderate	120/120 (100%)	120/120 (100%)
Nitrite	Positive	120/120 (100%)	120/120 (100%)
Protein	Trace	119/120 (99.17%)	120/120 (100%)
Urobilinogen	0.2 EU/dL	120/120 (100%)	120/120 (100%)
Leukocyte	Moderate	120/120 (100%)	120/120 (100%)
pH	8.0	119/120 (99.17%)	120/120 (100%)

**Control Level III (Negative)**

Analyte	Control Level III	Exact Match Agreement (%)	+/- 1 Color Block Agreement (%)
Glucose	Negative	120/120 (100%)	120/120 (100%)
Bilirubin	Negative	120/120 (100%)	120/120 (100%)
Ketone	Negative	120/120 (100%)	120/120 (100%)
Specific Gravity	1.010	120/120 (100%)	120/120 (100%)
Blood	Negative	120/120 (100%)	120/120 (100%)

Nitrite	Negative	120/120 (100%)	120/120 (100%)
Protein	Negative	120/120 (100%)	120/120 (100%)
Urobilinogen	0.2 EU/dL	120/120 (100%)	120/120 (100%)
Leukocyte	Negative	120/120 (100%)	120/120 (100%)
pH	6.0	120/120 (100%)	120/120 (100%)

### Point-of-care Precision

Precision of the Uritek TC-201 Urine Analyzer Test System was evaluated at three point-of-care sites using three levels of control solution (negative, low positive, and high positive). At each site, three operators used three test strip lots and one analyzer to test each sample in duplicate for two runs per day for 10 days.

Results for all sites combined are summarized below:

Analyte	Control Level I (High Positive)		Control Level II (Low Positive)		Control Level III (Negative)	
	Exact Match	±1 Color Block Agreement	Exact Match	±1 Color Block Agreement	Exact Match	±1 Color Block Agreement
Glucose	100% (120/120)	100% (120/120)	100% (120/120)	100% (120/120)	100% (120/120)	100% (120/120)
Bilirubin	100% (120/120)	100% (120/120)	99.17% (119/120)	100% (120/120)	100% (120/120)	100% (120/120)
Ketone	100% (120/120)	100% (120/120)	100% (120/120)	100% (120/120)	100% (120/120)	100% (120/120)
Specific Gravity	99.17% (119/120)	100% (120/120)	100% (120/120)	100% (120/120)	100% (120/120)	100% (120/120)
Blood	100% (120/120)	100% (120/120)	99.17% (119/120)	100% (120/120)	100% (120/120)	100% (120/120)
Nitrite	100% (120/120)	100% (120/120)	100% (120/120)	100% (120/120)	100% (120/120)	100% (120/120)
Protein	100% (120/120)	100% (120/120)	100% (120/120)	100% (120/120)	100% (120/120)	100% (120/120)
Urobilinogen	99.17% (119/120)	100% (120/120)	100% (120/120)	100% (120/120)	100% (120/120)	100% (120/120)
Leukocyte	100% (120/120)	100% (120/120)	99.17% (119/120)	100% (120/120)	100% (120/120)	100% (120/120)

Analyte	Control Level I (High Positive)		Control Level II (Low Positive)		Control Level III (Negative)	
	Exact Match	±1 Color Block Agreement	Exact Match	±1 Color Block Agreement	Exact Match	±1 Color Block Agreement
pH	98.33% (118/120)	100% (120/120)	98.33% (118/120)	100% (120/120)	100% (120/120)	100% (120/120)

b. *Linearity/assay reportable range:*

The study to evaluate the reportable range (percent recovery) for each semi-quantitative level of the Uritek TC-201 Urine Chemistry Test System was performed by measuring a negative urine and a negative urine pool spiked with known increasing and decreasing concentrations of analytes relative to each semi-quantitative level. Samples were measured in replicates of eight by three operators on three reagents strip lots for a total of 24 measurements for every sample. A pH meter was used to confirm the pH results. The specific gravity was confirmed by a clinical, handheld refractometer.

The percent recovery for each analyte at each concentration block is shown in the table below:

Analyte	Color Block Output Units (Reportable Range)		Concentration Tested	Percent Exact Match
	Arbitrary	Conventional		
Glucose	-	0 mg/dL	0 mg/dL	100%
	±	100 mg/dL	100 mg/dL	100%
	1+	250 mg/dL	250 mg/dL	100%
	2+	500 mg/dL	500 mg/dL	100%
	3+	1000 mg/dL	1000 mg/dL	100%
Bilirubin	-	Negative	0 mg/dL	100%
	1+	Small	1.0 mg/dL	100%
	2+	Moderate	2.0 mg/dL	100%
	3+	Large	4.0 mg/dL	100%
Ketone	-	Negative	0 mg/dL	100%
	±	Trace	5.0 mg/dL	100%
	1+	15 mg/dL	15 mg/dL	100%
	2+	40 mg/dL	40 mg/dL	100%
	3+	80 mg/dL	80 mg/dL	100%
Blood	-	Negative	0 Ery/μL	100%
	±	Trace	10 Ery/μL	100%
	1+	Small	25 Ery/μL	100%
	2+	Moderate	80 Ery/μL	100%
	3+	Large	200 Ery/μL	100%
Protein	-	Negative	0 mg/dL	100%

Analyte	Color Block Output Units (Reportable Range)		Concentration Tested	Percent Exact Match
	Arbitrary	Conventional		
	±	Trace	15 mg/dL	90%
	1+	30 mg/dL	30 mg/dL	100%
	2+	100 mg/dL	100 mg/dL	95%
	3+	300 mg/dL	300 mg/dL	95%
Nitrite	-	Negative	0 mg/dL	100%
	+	Positive	0.1 mg/dL	100%
Leukocyte	-	Negative	0 ca cells/μL	95%
	±	Trace	15 ca cells/μL	95%
	1+	Small	70 ca cells/μL	95%
	2+	Moderate	125 ca cells/μL	100%
	3+	Large	500 ca cells/μL	100%
Urobilinogen	0.2	0.2 EU/dL	0.2 EU/dL	100%
	1.0	1.0 EU/dL	1.0 EU/dL	100%
	2.0	2.0 EU/dL	2.0 EU/dL	90%
	4.0	4.0 EU/dL	4.0 EU/dL	100%
	8.0	8.0 EU/dL	8.0 EU/dL	100%
pH	5.0	5.0	5.0	95%
	6.0	6.0	6.0	95%
	6.5	6.5	6.5	95%
	7.0	7.0	7.0	95%
	7.5	7.5	7.5	95%
	8.0	8.0	8.0	100%
	8.5	8.5	8.5	100%
SG	1.005	1.005	1.005	100%
	1.010	1.010	1.010	100%
	1.015	1.015	1.015	100%
	1.020	1.020	1.020	100%
	1.025	1.025	1.025	100%
	1.030	1.030	1.030	100%

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

The Uritek TC-201 Urine Analyzer performs a 10 second system calibration using a white reflective check area at the back of the test strip bed prior to analyzing a test strip.

The urine test strip stability was established in k905396 to support storage between 15-30°C (59-86°F) at 20-30% humidity out of direct sunlight for 2 years, and to support an open-vial stability of 90 days at room temperature (15-30°C).

d. *Detection limit:*

A study was performed to validate the cut-off concentration for each semi-quantitative level measured by the Uritek TC-201 Urine Chemistry Test System. Samples were prepared by spiking a negative urine pool with a minimum of four levels across the measuring range for each analyte concentration. The samples were analyzed in replicates of eight by three operators on three reagent strip lots, for a total of 24 data points for each level. The low cut-off concentration for each color block was defined as the lowest concentration at which >55% of the test results are positive.

The cut-off values and percentage sensitivity for each color block for individual analyte is summarized and demonstrated in the table below:

Analyte	Color Block	Cut-off	% Positive Results
Glucose	100 mg/dL	75 mg/dL	67%
	250 mg/dL	212.5 mg/dL	83%
	500 mg/dL	437.5 mg/dL	83%
	1000 mg/dL	875 mg/dL	75%
Bilirubin	Small	0.5 mg/dL	59%
	Moderate	1.75 mg/dL	87.5%
	Large	3.0 mg/dL	62.5%
Ketone	Trace	3.75 mg/dL	71%
	15 mg/dL	10 mg/dL	71%
	40 mg/dL	27.5 mg/dL	91%
	80 mg/dL	60 mg/dL	75%
Blood	Trace	7.5 Ery/ $\mu$ L	71%
	Small	21.25 Ery/ $\mu$ L	75%
	Moderate	52.5 Ery/ $\mu$ L	67%
	Large	170 Ery/ $\mu$ L	71%
Protein	Trace	11.25 mg/dL	91%
	30 mg/dL	26.25 mg/dL	75%
	100 mg/dL	65 mg/dL	87%
	300 mg/dL	200 mg/dL	87%
Nitrite	Positive	0.075 mg/dL	58%
Leukocyte	Trace	11.25 ca cells/ $\mu$ L	58%
	Small	56.25 ca cells/ $\mu$ L	67%
	Moderate	111.25 ca cells/ $\mu$ L	58%
	Large	312.5 ca cells/ $\mu$ L	67%
Urobilinogen	0.2 mg/dL	0.2 mg/dL	100%
	1.0 mg/dL	0.8 mg/dL	71%
	2.0 mg/dL	2.0 mg/dL	90%
	4.0 mg/dL	3.5 mg/dL	55%
	8.0 mg/dL	7.0 mg/dL	85%
pH	5.0	5.0	96%
	6.0	6.0	100%
	6.5	6.5	96%

Analyte	Color Block	Cut-off	% Positive Results
	7.0	7.0	96%
	7.5	7.5	96%
	8.0	8.0	96%
	8.5	8.5	96%
SG	1.005	1.005	92%
	1.010	1.010	92%
	1.015	1.015	92%
	1.020	1.020	92%
	1.025	1.025	92%
	1.030	1.030	92%

e. *Analytical specificity:*

Potential endogenous interferents and drugs commonly found in urine were evaluated to assess the interfering effect of various substances on the performance of the Uritek TC-201 Urine Chemistry Test System. Testing was performed using three urine pools with negative, low positive and positive concentrations for all analytes. At least two levels of the listed interferents were added. Each urine sample was tested in triplicate. The individual results of the samples spiked with the interfering substance at the stated concentration were compared against the control sample with no interfering substance. Interference was defined as a change in output of  $\pm 1$  color blocks between spiked and unspiked control sample.

The concentrations of the potential interfering substances that did not have any influence on the test results are listed below:

Potential Interfering Substance	Highest Concentration at which no interference was observed
Ascorbic Acid	30 mg/dL
Ammonium Chloride	200 mg/dL
Albumin	$\leq 125$ mg/dL
Bilirubin	8 mg/dL
Creatine	10 mg/dL
Lithium Acetoacetate	$\leq 60$ mg/dL
Calcium Chloride	275 mg/dL
Citric Acid	75 mg/dL
Creatinine	400 mg/dL
D (+) Glucose	2000 mg/dL
Glycine	450 mg/dL
Hemoglobin	10 mg/dL
Potassium Chloride	1500 mg/dL
Sodium Chloride	6000 mg/dL
Oxalic Acid	70 mg/dL
Sodium Acetate	25 mg/dL
Sodium Bicarbonate	750 mg/dL

Sodium Nitrate	10 mg/dL
Sodium Nitrite	10 mg/dL
Sodium Phosphate	500 mg/dL
Uric Acid	150 mg/dL
Urea	4000 mg/dL
Riboflavin	10 mg/L
Theophylline	100 mg/L
D (+) Galactose	80 mg/dL
Fructose	100 mg/dL
Lactose	10 mg/dL
Leucocytes	3000 cells/ $\mu$ L
Blood	$\leq$ 0.01%
Human Immunoglobulins	25 mg/dL
Formalin	92.5 mg/dL
Amoxicillin	30 mg/dL
Nitrofurantoin	60 mg/dL
Gentamicin sulfate	6 mg/dL
Acetaminophen	40 mg/dL

The following table shows the substances which did interfere with one or more of the Teco Diagnostics URS-10 strip analytes. Results are expressed as the lowest concentration of interfering substance that exhibited interference and the resulting change in output of color block.

Analyte	Concentration of Substance at which Interference was observed	Change in Color block Output
Glucose	Blood ( $\geq$ 5%), Hypochlorite ( $\geq$ 0.6%), Pyridium ( $\geq$ 50 mg/dL)	+1,
	Ascorbic Acid ( $\geq$ 75 mg/dL), Amoxicillin ( $\geq$ 100 mg/dL), Acetylcysteine ( $\geq$ 135 mg/dL)	-1
Protein	Hemoglobin ( $\geq$ 20 mg/dL), Blood ( $\geq$ 1%), Sodium Bicarbonate (1500 mg/dL), Chloroquine ( $\geq$ 20 mg/dL), Pyridium ( $\geq$ 50 mg/dL), pH ( $>$ 8.5)	+1, +2 to +3, +1 to +2, +1
	Amoxicillin ( $\geq$ 100 mg/dL), Hypochlorite ( $\geq$ 0.6%), SG ( $>$ 1.030)	-1
Bilirubin	Blood ( $\geq$ 5%), Pyridium ( $\geq$ 50 mg/dL)	+2 to +3
	Formalin ( $\geq$ 185 mg/dL), Boric Acid ( $\geq$ 500 mg/dL), Acetylcysteine ( $\geq$ 67.5 mg/dL), Hypochlorite ( $\geq$ 0.6%)	-1
Urobilinogen	Blood ( $\geq$ 1%)	+1
	Hypochlorite ( $\geq$ 0.6%)	-2
SG	Albumin ( $\geq$ 200 mg/dL), Blood (1%)	+1
	Nitrofurantoin ( $\geq$ 120 mg/dL)	-1 to -2

pH	SG (> 1.030), Sodium Bicarbonate (≥ 750 mg/dL), Sodium Phosphate (≥ 250 mg/dL), Creatinine (≥ 400 mg/dL)	+1 to +2
	Ascorbic Acid (≥75 mg/dL), Calcium Chloride (≥ 275 mg/dL) Citric Acid (≥ 75 mg/dL), Sodium Chloride (≥ 6000 mg/dL), Oxalic Acid (≥ 70 mg/dL)	-1 to -2
Blood	Albumin (200 mg/dL), Hypochlorite (≥ 0.6%)	+2
	Acetylcysteine (≥ 67.5 mg/dL)	-1
Nitrite	Blood (≥ 1%), Hypochlorite (≥ 0.6%), Pyridium (≥ 50 mg/dL)	+1
Leukocytes	Blood (≥ 1%), Pyridium (≥ 50 mg/dL)	+1 to +2,
	Glucose (≥ 2000 mg/dL), Boric Acid (≥ 500 mg/dL), Chloroquine (≥ 20 mg/dL), Amoxicillin (≥ 100 mg/dL), Hypochlorite (≥ 0.6%)	-1, -1 to -2
Ketone	Blood (≥ 5%), Acetylcysteine (≥ 67.5 mg/dL), Pyridium (≥ 50 mg/dL)	+1, +2 to +3
	Hypochlorite (≥ 0.6%)	-1 to -2

In addition to the interference described in the table above, the labeling includes limitations that the following substances may interfere with one or more analytes on the Uritek TC-201 Urine Chemistry Test System:

Quarternary ammonium complexes

Chlorpromazine

Rafampen

Indican

Lodine metabolites

Drugs containing azo dyes

Microbial peroxidase

Cephalexin

MESNA

Phenylketones

L-Dopa

#### pH Interference Study

An additional study to evaluate the effect of sample pH on the test results for the ten analytes in human urine was performed. The study result shows that sample pH from 5.0 to 9.0 does not affect the test results for leukocytes, urobilinogen, ketone, pH, blood, nitrite, bilirubin and glucose. Samples with pH greater than 8.5 affected the protein test resulting in a false high result.

#### Specific Gravity Interference Study

An additional study was performed to evaluate the effect of sample specific gravity on the test results for the ten analytes in human urine. The study result shows that sample specific gravity from 1.000 to 1.040 does not affect the test results for

leukocytes, urobilinogen, ketone, blood, nitrite, bilirubin and glucose. Samples with specific gravity greater than 1.030 affected the pH and protein tests resulting in a false low result.

The labeling includes the effects from pH and specific gravity as limitations of the procedure.

Sample carry-over study

The interference of samples running over from one pad to the adjacent pad on the performance of the Uritek TC-201 Urine Chemistry Test System was evaluated. Prior to testing, the strip was dipped into commercially available urine control solutions (negative, low positive, high positive) and was then held upward to allow the sample to flow from the leukocyte pad to the next aligned pads or held downward to allow the sample flow from the glucose pad to the next aligned pads. Each holding method was tested in 3 replicates. The results support the claims that test results are not affected by sample carry-over.

*f. Assay cut-off:*

Not applicable.

2. Comparison studies:

*a. Method comparison with predicate device:*

A method comparison study was performed at three point-of-care sites using a single replicate of 392 clinical urine samples between the Urine Reagent (URS-10) Strips on the TC-201 Urine Analyzer and the Siemens Multistix 10 SG Reagent Strips on the Siemens Clinitek Status+ Urine Analyzer. 11% of the total samples were contrived (44 samples). At each site, six operators performed the testing using one lot of URS-10 test strips and one analyzer.

Additional method comparison data was obtained from POC Site I and Site II for 117 clinical samples. The total number of patient urine specimens evaluated in the method comparison study is 509.

Testing results are summarized in the following tables.

Glucose		Siemens Clinitek Status + Urine Analyzer					
3 Sites, N=509		1000	500	250	100	Neg	Overall
Uritek TC-201 Urine Test System	1000	16	4	0	0	0	20
	500	4	37	0	0	0	41
	250	0	0	10	0	0	10
	100	0	0	0	25	0	25
	Neg	0	0	0	0	413	413
Total		20	41	10	25	413	509

Agreement within same color block (Exact Match)	80.00% (16/20)	90.24% (37/41)	100.0% (10/10)	100.0% (25/25)	100.0% (413/413)	98.43% (501/509)
Agreement within $\pm 1$ color block	100.0% (20/20)	100.0% (37/41)	100.0% (10/10)	100.0% (25/25)	100.0% (413/413)	100.0% (509/509)

Bilirubin		Siemens Clinitek Status + Urine Analyzer				
3 Sites, N=509		3+	2+	1+	Neg	Overall
Uritek TC-201 Urine Test System	3+	35	1	0	0	36
	2+	0	31	0	0	31
	1+	0	0	51	5	56
	Neg	0	0	0	386	386
Total		35	32	51	391	509
Agreement within same color block (Exact Match)		100.0% (35/35)	96.88% (31/32)	100.0% (51/51)	98.72% (386/391)	98.82% (503/509)
Agreement within $\pm 1$ color block		100.0% (35/35)	100.0% (32/32)	100.0% (51/51)	100.0% (391/391)	100.0% (509/509)

Ketone		Siemens Clinitek Status + Urine Analyzer					
3 Sites, N=509		80	40	15	Trace	Neg	Overall
Uritek TC-201 Urine Test System	80	13	1	0	0	0	14
	40	0	18	1	0	0	19
	15	0	0	24	1	0	25
	TRA	0	0	0	44	4	48
	Neg	0	0	0	1	402	403
Total		13	19	25	46	406	509
Agreement within same color block (Exact Match)		100.0% (13/13)	94.74% (18/19)	96.0% (24/25)	95.65% (44/46)	99.01% (402/406)	98.43% (501/509)
Agreement within $\pm 1$ color block		100.0% (13/13)	100.0% (19/19)	100.0% (25/25)	100.0% (46/46)	100.0% (406/406)	100.0% (509/509)

Specific Gravity		Siemens Clinitek Status + Urine Analyzer						
3 Sites, N=509		$\geq 1.030$	1.025	1.020	1.015	1.010	$\leq 1.005$	Overall
Uritek TC-201 Urine Test System	$>1.030$	57	5	0	0	0	0	62
	1.025	6	55	5	0	0	0	66
	1.020	0	21	112	10	0	0	143
	1.015	0	0	16	135	6	0	157
	1.010	0	0	0	8	40	7	55
	$<1.005$	0	0	0	0	4	22	26
Total		63	81	133	153	50	29	509
Agreement within same color block (Exact Match)		90.48% (57/63)	67.90% (55/81)	84.21% (112/133)	88.24% (135/153)	80.0% (40/50)	75.86% (22/29)	82.71% (421/509)

Agreement within $\pm 1$ color block	100.0% (63/63)	100.0% (81/81)	100.0% (133/133)	100.0% (153/153)	100.0% (50/50)	100.0% (29/29)	100.0% (509/509)
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Blood		Siemens Clinitek Status + Urine Analyzer					
3 Sites, N=509		3+	2+	1+	Trace	Neg	Overall
Uritek TC-201 Urine Test System	3+	32	3	0	0	0	35
	2+	0	55	0	0	0	55
	1+	0	0	21	0	0	21
	Trace	0	0	1	63	2	66
	Neg	0	0	0	4	328	332
Total		32	58	22	67	330	509
Agreement within same color block (Exact Match)		100.0% (32/32)	94.83% (55/58)	95.45% (21/22)	94.03% (63/67)	99.39% (328/330)	98.04% (499/509)
Agreement within $\pm 1$ color block		100.0% (32/32)	100.0% (58/58)	100.0% (22/22)	100.0% (67/67)	100.0% (330/330)	100.0% (509/509)

Protein		Siemens Clinitek Status + Urine Analyzer					
3 Sites, N=509		>300	100	30	Trace	Neg	Overall
Uritek TC-201 Urine Test System	>300	26	0	0	0	0	26
	100	0	35	0	0	0	35
	30	0	3	34	0	0	37
	Trace	0	0	2	46	6	54
	Neg	0	0	0	3	354	357
Total		26	38	36	49	360	509
Agreement within same color block (Exact Match)		100.0% (26/26)	92.11% (35/38)	94.44% (34/36)	93.88% (46/49)	98.33% (354/360)	97.25% (495/509)
Agreement within $\pm 1$ color block		100.0% (26/26)	100.0% (38/38)	100.0% (36/36)	100.0% (49/49)	100.0% (360/360)	100.0% (509/509)

Urobilinogen		Siemens Clinitek Status + Urine Analyzer					
3 Sites, N=509		>8.0	4	2	1	0.2	Overall
Uritek TC-201 Urine Test System	>8.0	31	0	0	0	0	31
	4.0	0	26	0	0	0	26
	2.0	0	0	22	0	0	22
	1.0	0	0	0	14	0	14
	0.2	0	0	0	2	414	416
Total		31	26	22	16	414	509
Agreement within same color block (Exact Match)		100.0% (31/31)	100.0% (26/26)	100.0% (22/22)	87.5% (14/16)	100.0% (414/414)	99.61% (507/509)
Agreement within $\pm 1$ color block		100.0% (31/31)	100.0% (26/26)	100.0% (22/22)	100.0% (16/16)	100.0% (414/414)	100.0% (509/509)

pH		Siemens Clinitek Status + Urine Analyzer							
3 Sites, N=509		8.5	8.0	7.5	7.0	6.5	6.0	5.0	Overall
Uritek TC-201 Urine Test System	8.5	36	0	0	0	0	0	0	36
	8.0	2	15	5	0	0	0	0	22
	7.5	1	1	34	1	0	0	0	37
	7.0	0	0	0	100	0	0	0	100
	6.5	0	0	0	8	65	1	0	74
	6.0	0	0	0	0	11	89	8	108
	5.0	0	0	0	0	1	9	122	132
	Total	39	16	39	109	77	99	130	509
Agreement within same color block (Exact Match)		92.31% (36/39)	93.75% (15/16)	87.18% (34/39)	91.74% (100/109)	84.42% (65/77)	89.90% (89/99)	93.85% (122/130)	90.57% (461/509)
Agreement within ±1 color block		97.44% (38/39)	100.0% (16/16)	100.0% (39/39)	100.0% (109/109)	98.70% (76/77)	100.0% (99/99)	100.0% (130/130)	99.61% (507/509)

Nitrite		Siemens Clinitek Status + Urine Analyzer		
3 Sites, N=509		POS	NEG	Overall
Uritek TC-201 Urine Test System	POS	80	2	82
	NEG	1	426	427
	Total	81	428	509
Agreement within same color block (Exact Match)		98.77% (80/81)	99.53% (426/428)	99.41% (506/509)
Agreement within ±1 color block		N/A	N/A	N/A

Leukocyte		Siemens Clinitek Status + Urine Analyzer					
3 Sites, N=509		3+	2+	1+	Trace	Neg	Overall
Uritek TC- 201 Urine Test System	3+	39	0	0	0	0	39
	2+	0	12	0	0	0	12
	1+	0	1	49	0	0	50
	Trace	0	0	1	27	7	35
	Neg	0	0	0	2	371	373
	Total	39	13	50	29	378	509
Agreement within same color block (Exact Match)		100.0% (31/31)	100.0% (26/26)	100.0% (22/22)	87.5% (14/16)	100.0% (414/414)	99.61% (507/509)
Agreement within ±1 color block		100.0% (39/39)	100.0% (12/13)	100.0% (50/50)	100.0% (29/29)	100.0% (378/378)	100.0% (509/509)

*b. Matrix comparison:*

Not applicable. Urine is the only sample 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):*

Not applicable.

4. Clinical cut-off:

Not applicable.

5. Expected values/Reference range:

The labeling states the following:

**Glucose:** Small amounts of glucose are normally excreted by the kidney.<sup>5</sup> Concentrations as little as 0.1 g/dl glucose, read either at 10 or 30 seconds, may be significantly abnormal if found consistently. At 10 seconds, results should be interpreted qualitatively; for semi-quantitative results, read at 30 seconds only.

**Bilirubin:** Normally, no bilirubin is detectable in urine by even the most sensitive method. Even trace amounts of bilirubin are sufficiently abnormal to require further investigation. Atypical colors (colors produced which are different than the negative or positive color blocks shown on the Color Chart) may indicate that bilirubin derived bile pigments are present in the urine sample and are possibly masking the bilirubin reaction.

**Ketone:** Normally, no ketones are present in urine. Detectable levels of ketone may occur in urine during physiological stress conditions such as fasting, pregnancy, and frequent strenuous exercise.<sup>6-8</sup> In starvation diets, or in other abnormal carbohydrate metabolism situation, ketones appear in the urine in excessively large amounts before serum ketones are elevated.<sup>9</sup>

**Specific Gravity:** Random urine may vary in specific gravity from 1.003-1.040+. Twenty-four hour urine from normal adults with normal diets and normal fluid intake will have a specific gravity of 1.016-1.022.<sup>10</sup>

**Blood:** Any green spots or green color developing on the reagent area within 40 seconds is significant and the urine should be examined further. Blood is frequently, but not invariably found in the urine of menstruating females.

**pH:** The normal pH of urine can range from 4.5-8.0. The average pH values in healthy subjects is 6.0.<sup>3</sup>

**Protein:** In 24-hour urine, 1-14 mg/dl of protein may be excreted by the normal kidney.<sup>4</sup> A color matching any color block greater than trace indicates significant proteinuria. For urine with high specific gravity, the test area may most closely match the trace color block even though only normal concentrations of protein are present. Clinical judgment is needed to evaluate the significance of trace results.

**Urobilinogen:** In a healthy population, the normal urine urobilinogen range obtained with this test is 0.2-1.0 Ehrlich Unit/dL. A result of 2.0 EU/dL may be of clinical significance and the same patient sample should be evaluated further.

**Nitrite:** Normally no detectable amount of nitrite is present in urine.<sup>3</sup> The nitrite area will be positive in a proportion of cases of significant infection, depending on how long the urine specimens were retained in the bladder prior to collection. Retrieval of positive cases with the nitrite test range from as low as 40%, in instances where little bladder incubation occurred, to as high as 80% in instances where a minimum of 4 hours incubation occurred.

**Leukocytes:** Normal urine specimens generally yield negative results with this test. A trace result may be of questionable clinical significance and it is recommended that the test be repeated using a fresh sample from the same patient. Repeated trace and positive results are of clinical significance.

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**P. Other Supportive Instrument Performance Characteristics Data Not Covered In The “Performance Characteristics” Section above:**

Flex Study – Temperature and Humidity

The environmental effect on the performance of the Uritek TC-201 Urine Chemistry Test System was evaluated by placing the test strips in relative humidity of <20%, 30%, 50%, 60% and 70% environment at 15°C and 45°C. Strips were removed at 0.5h, 1h, 2h, 4h, 8h, 16h and 24h for testing in triplicate using commercially available urine control solutions at Level I (High analyte concentration), Level II (Low analyte concentration) and Level III (Negative). The study results support the claim that the test strips are stable at 15-30°C (59-86°F) at 20-30% humidity.

Flex Study – Timing of Urine Dip

A study was performed to demonstrate that there is no impact in results for Uritek TC-201 Urine Chemistry Test System when the strips are dipped in urine for 1-10 seconds. The labeling states that the dipping step should not exceed 10 seconds.

Analyzer Operating Conditions Study

A study was performed to support the claim of acceptable operating conditions at 15-30°C and 18-80% Relative Humidity for the Uritek TC-201 Urine Analyzer. The performance of Uritek TC-201 Urine Chemistry Test System was evaluated by placing the Uritek TC-201 Urine analyzer in relative humidity of 92% at 30°C. These conditions were manufactured artificially in the Laminar Air Flow Cabinet by placing Hot Water Steam Bath and a Humidifier. Tests were performed at particular time-points at 0.1h, 8h, 16h and 24h using commercially available urine control solutions at Level I (High analyte concentration), Level II (Low analyte concentration) and Level III (Negative).

The Uritek TC-201 Urine Analyzer device complies with the applicable voluntary standards which include IEC 61010-1 and IEC 61010-2-101 for Electrical Safety and IEC 61326-1 and IEC 61326-2 for Electromagnetic Compatibility.

**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.