CLIA Waiver by Application Approval Determination

Decision Summary

A. Document Number

CW190011

B. Parent Document Number

K160372

C. CLIA Waiver Type:

CLIA Waiver by Application

D. Applicant

Teco Diagnostics

E. Proprietary and Established Names

Uritek TC-201 Urine Chemistry Test System

F. Measurand (analyte)

Urine Glucose, Blood, Leukocytes, Specific Gravity, pH, Nitrite, Protein, Ketones, Urobilinogen and Bilirubin

G. Sample Type(s)

Urine with no preservatives

H. Type of Test

Semi-quantitative and qualitative urinalysis

I. Test System Description

The Uritek TC-201 Urine Chemistry Test System consists of the Uritek TC-201 Urine Analyzer and the Teco Diagnostics Urine Reagent (URS-10) Strips.

The Uritek TC-201 Urine Analyzer is a portable, automated, bench top instrument used to read Teco Diagnostics' Urine Reagent (URS-10) Strips, show the results on a liquid crystal display (LCD) screen and print the results.

The Teco Diagnostics Urine Reagent (URS-10) Strips are plastic strips with reagent color blocks that can semi-quantitatively measure glucose, bilirubin, ketone, specific gravity, blood, pH, protein, urobilinogen, nitrite, and leukocytes in urine, based on color changes using chemical reactions.

J. Demonstrating "Simple"

- The Uritek TC-201 Urine Chemistry Test System consists of the fully automated Uritek TC-201 Urine Analyzer and single-use Teco Diagnostics Urine Reagent (URS-10) Strips.
- The Uritek TC-201 Urine Chemistry Test System uses direct, unprocessed urine specimens. The Uritek TC-201 Urine Chemistry Test System requires no specimen manipulation before performing the test procedure.
- There is no reagent handling, reagents are secured within the pads of the test strip. Once the strip is dipped into the urine specimen cup and blotted, it is then placed on the strip holder and the "START" button is pushed. There are no further procedural steps.
- The Uritek TC-201 Urine Chemistry Test System requires no operator intervention during the analysis steps.
- The Uritek TC-201 Urine Chemistry Test System requires no technical or specialized training with respect to troubleshooting or interpretation of multiple or complex error codes. Error messages are unambiguous and include easy-to-interpret solutions.
- The Uritek TC-201 Urine Chemistry Test System requires no electronic or mechanical maintenance. The CLIA waived version of the instrument and reagent strips are factory-sealed and cannot be adjusted by the user. Maintenance consists of general external cleaning of the instrument.
- The Uritek TC-201 Urine Chemistry Test System provides direct readout of semi-quantitative results, i.e. requires no interpretation, calculation, or calibration by the operator.
- The Uritek TC-201 Urine Chemistry Test System include a quick start guide (QSG) instruction and troubleshooting guide with simple error codes that are written at no higher than a 7th grade reading level.

K. Demonstrating "Insignificant Risk of an Erroneous Result"- Failure Alerts and Fail-safe Mechanisms

1. Risk Analysis

A comprehensive risk analysis for The Uritek TC-201 Chemistry Test System was conducted according to ISO 14971 and Failure Modes and Effects Analysis (FMEA) methods were utilized to assess the risks of providing the incorrect result for a patient and the safety risks that may affect the patient or the operator associated with the operation of the Uritek TC-201 Chemistry Test System. All risks of harm to the patient or operator were mitigated to an acceptable level and were supported by flex studies and/or operator instructions.

2. Fail-Safe and Failure Alert Mechanisms

a. Error Messages

The system will provide an error message, or a lockout function will be triggered and will not allow output of test results for the following conditions:

- Software system failure: 'System Calibration Failed' error message
- Optics failure: "Optical System Fail" error message
- Electronics failure: 'Electronic System Fail' error message
- Motor fails/strip bed jams: 'Mechanical System Fail' error message
- Improper installation of strip bed: 'Mechanical System Fail' error message.
- Improper placement of strips on test strip bed:
  - 'Misplaced Strip' error message when the strip is tilted/ or there is no strip.
  - 'Incorrect Strip Type' error message when strip is placed upside down or backwards.
- Dry strip used/ incorrect wetting of strips: 'Dry Strip Detected' error message
- Incorrect type of strips used: 'Incorrect Strip Type' error message
- Use of improperly stored strips: 'Strip Quality Issue' error message
- Use of an already dipped test strip: 'Strip Quality Issue' error message
- Use of expired strips: 'Strip Quality Issue' error message
- Expired strip bottle used: 'Barcode Error' error message
- Calibration failure: 'Optical System Fail' error message
- Expired controls used /selection of incorrect controls / improperly stored controls used:
  - 'QC Test Fail' error message
  - 'Barcode Error' error message
- Interference due to blood in urine specimen: 'Possible false positive results due to blood interference may occur for glucose, protein, bilirubin, urobilinogen, nitrite, leukocytes, ketone' error message

b. Stability of calibration

The Uritek TC-201 Urine Analyzer performs an automatic 10 second system calibration using a white reflective check area at the back of the test strip bed prior to analyzing a test strip and requires no operator intervention during calibration.

c. External Control Materials

Teco Urinalysis Quality Control Solutions Level I and II are provided with the system and are used to demonstrate that the system is performing properly.

- The Quick Start Guide, Operator Manual and the package insert state that Teco Urinalysis Quality Control Solutions Level I and II must be tested under the following conditions for CLIA waived settings:

- When a new canister of reagent strips is opened
- When test results seem inaccurate
- When a new operator uses the analyzer
- Each new day of testing
- After performing maintenance or service on the analyzer

- Storage and stability - The user should follow the manufacturer's instructions for storage and stability.

3. Flex Studies

The following flex studies were conducted on the Uritek TC-201 Urine Chemistry Test System. The studies were conducted using Uritek TC-201 Urine Analyzer, the Teco Urine Reagent Strips URS-10 (glucose, bilirubin, ketone, specific gravity, blood, pH, protein, urobilinogen, nitrite, and leukocytes) and contrived urine pools (see Table below for measurand levels).

Concentration of Sample Pools used in Flex Studies

Analyte	Concentrations Tested				
	Sample Pool I	**Sample Pool II**	**Sample Pool III**	**Sample Pool IV**	**Unit**
Glucose	(b) (4)				mg/dL
Protein					mg/dL
Bilirubin					mg/dL
Urobilinogen					EU/dL
pH					-
Blood					Ery/µL
SG					-
Ketone					mg/dL
Nitrite					mg/dL
Leukocytes					ca Cells/µL

All testing was performed in duplicate on three analyzers.

a. Operator Error/Human Factors:

i. Incorrect placement of device (tilting):
In this study, the entire work surface was tilted to varying angles and the analyzer was place at different orientations on the work surface. Below is a list of the work surface tilt angles and the orientation of the analyzer on the surface.
- tilted left 0, 10, 15, and 20 degrees
- tilted right 0, 10, 15, and 20 degrees
- tilted front 0, 10, 15, and 20 degrees

- tilted back 0, 10, 15, and 20 degrees

The testing was performed with contrived sample pools showing that at up to 20° (the maximum inclination tested), a correct result was obtained 100% of the time.

ii. Incorrect placement of the strip on the device:
    - The strip was placed at distances of 0, 2, 5 and 7.5 mm from the end of the strip bed. Results showed that when the distance was larger than 5 mm, an error message indicating incorrect placement of the strip ("Misplaced Strip") was displayed on the screen. The correct result was obtained at 0 and 2 mm distance from the end of the strip bed.
    - Results showed that when strips were placed such that they were tilted on the strip bed, the instrument returned the error "Misplaced Strip".
    - When the strip was placed upside down or backwards on the strip bed, the device returned the error "Incorrect Strip Type".

iii. Strip reuse/delayed testing: Strips were dipped in urine and not placed on the strip bed before it retracted into the device. The device returned the error code "Misplaced Strip". The device was then set to perform the test and the strip that had already been dipped was placed on the strip bed. The device returned the error "Strip Quality Issue".

iv. Excess urine on reagent pads: strips were dipped into urine and then placed on the strip bed without blotting. All results were exact color block matches to control condition where strips were dipped and blotted according to the manufacturer's instructions.

v. Incomplete wetting of strips: the Teco Diagnostics Urine Reagent (URS-10) Strips were tested under the following conditions:
    - fully wetted
    - partially wetted
    - unwetted (dry)

The test results demonstrated that the Uritek TC-201 analyzer displayed a "Dry Strip Error" message 100% of the time when the strips were dry or partially wetted.

vi. Incorrect strips: other types of test strips from Teco and strips from different manufacturers were tested. Results showed that when other manufacturer's strips and other Teco strips were used, an error message "Incorrect Strip Type" was displayed on the screen.

vii. The dipping/wetting time is 10 seconds per the instructions for use. Increased and reduced dipping/wetting times were tested as follows.

- Strips were left in urine samples for 20 seconds before the test was started on the device (increased dipping time).
- Strips were dipped and removed from the urine samples. After 20 seconds, the test was started on the device, which starts a 10 second countdown before the strip bed retracts, thus a total of 30 seconds would elapse before the test strip was retracted into the device (increased wetting time).
- Strips were dipped in the urine just before the strip bed was retracted into the device (reduced wetting time).

All results matched testing under control condition of 10 seconds dipping/wetting time.

viii. The test strip was held vertically upward or downward after dipping in urine for at least 15 seconds to allow the urine sample flow from the leukocyte pad to the next aligned pads or from the glucose pad to the next aligned pads before testing. No interference was observed when the sample was allowed to run over from one reagent pad to another pad.

b. Operating Conditions

i. Different light conditions

The devices were tested under direct sunlight and under high intensity lights in close proximity (3 ft) focusing on the analyzers. No incorrect results were observed when the device was operated under direct sunlight and under high intensity lights in close proximity.

ii. High altitude

The devices were tested under conditions simulating high altitude conditions (>10,000 feet above sea level and oxygen content to 11.8%). No incorrect results were observed when the device was operated under conditions simulating high altitude conditions.

iii. Temperature and humidity

The Uritek TC-201 test system (Uritek TC-201 analyzers with URS-10 reagent strip bottles) was operated under the following extreme conditions: High Temp./High Humidity (40°C, 90%RH), High Temp./Low Humidity (40°C, <10%RH), Low temp./High Humidity (10°C, 90%RH) and Low Temp./Low Humidity (10°C, <10%RH) conditions. No incorrect results were observed when the device was operated under the specified extreme temperature and humidity conditions.

c. Specimen Integrity and Handling

i. A failure alert mechanism was developed and validated to mitigate the risk of reporting false positive results due to blood interference for glucose, protein, bilirubin, urobilinogen, nitrite, leukocytes, and ketone in urine tested with the Uritek TC-201 Urine Chemistry Test System in the hands of untrained users. When the amount of blood in a urine sample is measured as large, the failure alert mechanism is employed and flags the test result with the message "Possible false positive results due to blood interference may occur for glucose, protein, bilirubin, urobilinogen, nitrite, leukocytes, ketone". The alert message is printed on the paper test result, displayed on the analyzer LED screen and shown on the result which is sent to the electronic medical record. The alert message notifies the health care provider of potential false-positive results.

ii. Specimen storage stability: The device labeling instructs users to test urine samples no more than one (1) hour after collection and to discard urine samples after testing or if more than one hour has elapsed since collection.

d. Reagent Integrity

Studies were performed to assess how strips stored at extreme temperature and humidity conditions affect the performance of the device.

i. An open-foil, closed-vial study was conducted to monitor Teco Diagnostics Urine Reagent (URS-10) Strips integrity after the strips bottle has been opened for use. The following extreme temperature and humidity combinations were tested:

high temperature/high humidity (45°C/90% RH)
high temperature/low humidity (45°C/<20% RH)
room temperature/high humidity (22°C/90% RH)
room temperature/low humidity (22°C/<20% RH) which is the control condition
low temperature/high humidity (15°C/90% RH)
low temperature/low humidity (15°C/<20% RH)

Results showed that Teco Diagnostics Urine Reagent (URS-10) Strips were stable up to 4 weeks under high temperature and humidity conditions (45°C/90% RH) and were stable for 13 weeks (>90 days) under low temperature/low humidity (15°C/<20% RH), low temperature/high humidity (15°C/90% RH), and room temperature/low humidity (22°C/<20% RH). The maximum open-foil, closed-vial strips storage time claimed is 4 weeks. A user is alerted with 'Strip Quality Issue' error message if using expired strips.

ii. An open-canister study was conducted to monitor the integrity of Teco Diagnostics Urine Reagent (URS-10) Strips after the strip bottle has been

completely opened for use and not closed again (no caps/ lids). The following extreme temperature and humidity combinations were tested:

high temperature/high humidity (45°C/90% RH)
high temperature/low humidity (45°C/<20% RH)
room temperature/high humidity (22°C/90% RH)
room temperature/low humidity (22°C/<20% RH)
low temperature/high humidity (10°C/90% RH)
low temperature/low humidity (10°C/<20% RH)

Results showed that Teco Diagnostics Urine Reagent (URS-10) Strips were stable up to 7 days under high temperature and humidity conditions (45°C/90% RH) and room temperature/high humidity (22°C/90% RH). All the other conditions- high temp/low humidity (45°C, 20%RH), low temp/high humidity (10°C, 90%RH) and low temp/low humidity (10°C,20%RH) and room temp/low humidity (22°C, 20%RH) conditions were stable up to 10 days. After 7 days with an open seal and lid removed, the test strips degrade and the user is alerted with 'Strip Quality Issue' error message.

iii. Use of expired strips: Studies were performed to assess how expired test strips affect the performance of the device when the barcode scanner was turned on and when the barcode scanner was turned off.
- The barcode of the test strips bottle was first scanned before performing the test. Results showed that when expired test strips were used, an error message 'Barcode Error' was displayed on the screen.
- When the barcode scanner was turned off and testing was attempted with expired strips, the "Strip Quality Issue" error message was displayed.

e. <u>Hardware, software, and electronics integrity</u>

i. Power failure: the power cord was unplugged when the device was switched on and running a test. The device was then switched off manually, the power cord was re-plugged. The device was then turned on to evaluate the performance and the device performed as expected demonstrating that the device could tolerate sudden power loss.

ii. Incorrect voltage: the device was plugged in 220V (instead of 120V) outlet or 5V (instead of 9V) power cord was used. The device was then turned on to evaluate the performance and the device performed as expected demonstrating that the device could tolerate certain incorrect ranges of voltage.

iii. Repeated plugging and unplugging of the device: The device was plugged and unplugged 10 times. The device was then turned on to evaluate the performance and the device performed as expected demonstrating that the device could tolerate repeated plugging and unplugging.

iv. Hardware failure: to simulate hardware failure, a piece of plastic was placed in the strip bed to jam the strip bed. The device was then turned on and the strip bed jam triggered the Failure-Alert mechanism in the device as expected (i.e., errors for motor strip bed).

v. Optics failure: to simulate optics failure, the optics window was blocked. The device was then turned on and the blockage triggered the Failure-Alert mechanism in the device as expected (i.e., errors for optics).

vi. Electronic failure: to simulate electronic failure, the cable that connects the main board and the printer board was disconnected. The device was then turned on disconnected cable triggered the Failure-Alert mechanism in the device as expected (i.e., failure of electronics).

vii. Physical trauma to unit: a drop test was performed on three analyzers dropped from 4.5 feet. Testing showed that the device was able to function and give accurate results.

viii. Vibration testing: Three analyzers were placed within 1 foot of two centrifuges that were operating and could reach 15,000 RPM and 6000 RPM. Sample pools were tested, and all results were accurate.

ix. Electromagnetic Interference: Three analyzers with placed within one foot of the following devices that were turned on:

1. (b) (4) radio transistors
2. (b) (4) Wi-Fi routers
3. (b) (4) modem
4. (b) (4) cells phones
5. (b) (4) refrigerators
6. (b) (4) 240V ovens
7. (b) (4) miscellaneous electronic medical devices
8. Miscellaneous electronic laboratory equipment
9. (b) (4) desktop computers
10. (b) (4) voltage transformers

Sample pools were tested, and all results were accurate.

x. Cleaning cycle robustness: 280 weekly maintenance cleaning cycles (to simulate 5 years) were performed by removing the strip bed and wiping the bed with an alcohol pad. Sample pools were tested, and all results were accurate.

xi. Damage to calibration block: the white calibration block was broken in half and testing was attempted. Instruments returned an "Optical System Fail".

xii. Soiled calibration block: The system was tested with minute amounts and with visibly detectable amounts of urine sediment applied to the calibration block. No interference was observed for minute amounts of urine sediment applied to the calibration block and the test results were correct. When visibly detectable amounts of urine sediment were applied to the calibration block an error message "Optical System Fail" was displayed on the screen.

L. Demonstrating "Insignificant Risk of an Erroneous Result" – Accuracy

A. Clinical Study Design

The purpose of the clinical study was to evaluate the performance of the Uritek TC-201 Urine Chemistry Test System in the hands of the intended users when performed in CLIA waived-type settings.

1. Clinical Study Sites:
   Three clinical study sites in the U.S. were used in this study. The sites consisted of outpatient clinic, physician's office, and a specialty clinic.

2. Operators:
   A total of 18 operators with no training were recruited to represent CLIA-waived users. At each site, tests were performed by at least 3 untrained operators. The operators consisted of nurses (44%), receptionists (39%) and medical assistants (17%). Upon completion of the study, the operators at each site were asked to complete a questionnaire that asked them to rate the ease of use of the test procedure.

3. Instructions for Use
   The operators were given the instrument, reagent strips, operator's manual and quick reference guide.

4. Subjects (patients)
   Tests were performed on leftover urine samples from the clinics. No contrived or altered samples were tested in the clinical study.

B. Comparative Methods

The Comparative Methods (CM) for each analyte were traceable quantitative methods (when available) or validated, well documented semi-quantitative methods.

C. Statistical Analysis

The results of the Uritek TC-201 Chemistry Test System correspond to the following range of quantitative values:

Analyte	Color Block Output Units	Measuring Range
Glucose	Negative	0.0 – 75 mg/dL
	100 mg/dL	75 – 212.5 mg/dL
	250 mg/dL	212.5 – 437.5 mg/dL
	500 mg/dL	437.5 – 875 mg/dL
	1000 mg/dL	> 875 mg/dL
Bilirubin	Negative	0.0 – 0.5 mg/dL
	Small	0.5 – 1.5 mg/dL
	Moderate	1.75 – 3.0 mg/dL
	Large	> 3.0 mg/dL
Ketone	Negative	0.0 – 3.75 mg/dL
	Trace	3.75 – 10.0 mg/dL
	15 mg/dL	10.0 – 27.5 mg/dL
	40 mg/dL	27.5 – 60.0 mg/dL
	80 mg/dL	> 60.0 mg/dL
Blood	Negative	0 – 7.5 Ery/µL
	Trace	7.5 – 21.25 Ery/µL
	Small	21.25 – 52.5 Ery/µL
	Moderate	52.5 – 170 Ery/µL
	Large	> 170 Ery/µL
Protein	Negative	0.0 – 11.25 mg/dL
	Trace	11.25 – 26.25 mg/dL
	30 mg/dL	26.25 – 65 mg/dL
	100 mg/dL	65 – 200 mg/dL
	300 mg/dL	> 200 mg/dL
Nitrite	Negative	0.0 – 0.075 mg/dL
	Positive	> 0.075 mg/dL
Leukocyte	Negative	0 – 11.25 ca cells/µL
	Trace	11.25 – 56.25 ca cells/µL
	Small	56.25 – 111.25 ca cells/µL
	Moderate	111.25 – 406.25 ca cells/µL
	Large	> 406.25 ca cells/µL
Urobilinogen	0.2 mg/dL	0.2 – 0.6 mg/dL
	1.0 mg/dL	0.6 – 1.5 mg/dL
	2.0 mg/dL	1.5 – 3.0 mg/dL
	4.0 mg/dL	3.0 – 6.0 mg/dL
	8.0 mg/dL	> 6.0 mg/dL
pH	5.0 – 8.5	5.0 – 8.5
SG	1.005 – 1.030	1.005 – 1.030

1. Allowable Total Error (ATE) and Zones of Limits for Erroneous Results (LER)

The allowable total error (ATE) was set to ±10% for glucose, protein, pH and specific gravity. Based on this target, a range of quantitative values near the cutoff (near-cutoff range) was calculated. Because of the imprecision for these analytes, for CM test results in the near-cutoff range, the Waived Method (WM) test results could fall in either bin defined by that cutoff to be within the ATE. However, for CM test results outside of the near-cutoff ranges, only results within the corresponding WM bin was within the ATE (the ATE zones are presented in green color in the tables below in Section 2). For these analytes, the LER zones for the WM were set so that the disagreement with the CM is greater than ±1 color block and are presented in red color in the tables below in Section 2. The near cut-off ranges are described below:

a. Glucose

The allowable total error (ATE) was set to 10%. Based on this target, the near-cutoff ranges for glucose are presented below:

Cutoff	Near-cutoff range mg/dL
(b) (4) (cutoff between bins "0" and "180")	65 -78
(b) (4) (cutoff between bins "181" and "369")	181 - 219
(b) (4) (cutoff between bins "370" and "713")	370- 450
(b) (4) (cutoff between bins "714" and "1000")	713 - 871

For CM test results outside of the near-cutoff ranges only one corresponding bin of the semi-quantitative WM test was allowed.

b. Protein

The allowable total error (ATE) was set to 10%. Based on this target, the near-cutoff ranges for protein are presented below:

Cutoff	Near-cutoff range mg/dL
(b) (4) (cutoff between bins "0" and "21.85")	7.88 - 9.62
(b) (4) (cutoff between bins "21.86" and "51.7")	21.86 - 26.64
(b) (4) (cutoff between bins "51.8" and "143.1")	51.8 - 63.2
(b) (4) (cutoff between bins "143.2" and "300")	143.2- 174.8

For CM test results outside of the near-cutoff ranges only one corresponding bin of the semi-quantitative WM test was allowed.

c. pH
The allowable total error (ATE) was set to 10%. Based on this target, the near-cutoff ranges for pH are presented below:

Cutoff	Near-cutoff range
(b) (4) (cutoff between bins "≤5.40" and "6.15")	5.41 – 5.60
(b) (4) (cutoff between bins "6.16" and "6.65")	6.16 – 6.34
(b) (4) (cutoff between bins "6.66" and "7.15")	6.66 – 6.84
(b) (4) (cutoff between bins "7.16" and "7.65")	7.16 – 7.34
(b) (4) (cutoff between bins "7.66" and "8.15")	7.35 - 7.65
(b) (4) (cutoff between bins "8.16" and "9.0")	8.16 – 8.34

For CM test results outside of the near-cutoff ranges only one corresponding bin of the semi-quantitative WM test was allowed.

d. Specific gravity
The allowable total error (ATE) was set to 10%. Based on this target, the near-cutoff ranges for specific gravity are presented below:

Cutoff	Near-cutoff range
(b) (4) (cutoff between bins "1.005≤" and "1.011")	1.007 – 1.008
(b) (4) (cutoff between bins "1.012" and "1.016")	1.012 – 1.013
(b) (4) (cutoff between bins "1.017" and "1.021")	1.017 – 1.018
(b) (4) (cutoff between bins "1.022" and "1.026")	1.022 – 1.023
(b) (4) (cutoff between bins "1.027" and "1.030")	1.027 – 1.028

For CM test results outside of the near-cutoff ranges only one corresponding bin of the semi-quantitative WM test was allowed.

e. For the analytes where no quantitative comparator method was available, the sponsor conducted the following study:
Each sample was tested by untrained operators using the WM in singlicate. Each sample was also tested by each of 2 laboratory professionals using a semi quantitative CM in singlicate in a laboratory setting.

For samples where the professional operators obtained CM results in adjacent bins, because of the imprecision, the WM could fall in either bin and be within the ATE. However, if the professional operators obtained results in the same bin, the WM had to fall in that same bin to be within the ATE (the ATE zones are presented in green color in the tables below in section 2). The LER zones for the WM were set so that the disagreement with the CM is no greater than ±1 color block and are presented in red color in the tables below in section 2.

To support CLIA waiver, ≥ 95% of data points should fall within the ATE zone (green) for each color block or bin and 0% of results should fall within the LER (red) zone for each color block or bin.

2. Results of the Clinical Study

The clinical study evaluated the performance of the Uritek TC-201 Urine Chemistry Test System. The results showed the agreement of the CMs (run by lab professionals) and the WM (run by untrained operators). The results below for the combined sites are representative of the individual sites.

Combined Sites Results: GLUCOSE

		GLUCOSE CM (mg/dL)									
GLUCOSE		0 – 64	Near Cut-off 65-78	79-180	Near Cut-off 181-219	220-369	Near Cut-off 370-450	451-712.8	Near Cut-off 712.9 - 871.1	871.2-1000	Total
Predicted Bins		Neg	Neg or Trace	Trace	Trace or 1+	1+	1+ or 2+	2+	2+ or 3+	3+	
Uritek TC-201	Neg	342	6	2							350
	Trace	1	3	56	6						66
	1+				4	42	10				56
	2+						4	42	6	1	53
	3+									75	75
Total		343	9	58	10	42	14	42	6	76	600
% Exact Match Agreement		100%	100%	97%	100%	100%	100%	100%	100%	99%	99.3%

For Glucose,

- the overall exact match between the CM and the Proposed WM was 99.3% (596/600) with 95%CI: (98.3%; 99.7%),
- ≥ 97% of data points were within the ATE zone (green) for each color block
- 0% (0/600) of data points were within the LER (red) zone with 95%CI: (0.0%; 0.6%)

Combined Sites Results: PROTEIN

PROTEIN		PROTEIN CM (mg/dL)									
		0-7.87	Near Cutoff 7.88 - 9.62	9.63-21.85	Near Cutoff 21.86 - 26.64	26.65-51.7	Near Cutoff 51.8 - 63.2	63.3-143.1	Near Cutoff 143.2-174.8	174.9 -300	Total
Predicted Bins		Neg	Neg or Trace	Trace	Trace or 1+	1+	1+ or 2+	2+	2+ or 3+	3+	
Uritek TC-201	Neg	204	26	7							237
	Trace		4	155	42	1					202
	1+				3	74	14				91
	2+							28	7		35
	3+								6	29	35
Total		204	30	162	45	75	14	28	13	29	600
% Exact Match Agreement		100%	100%	96%	100%	99%	100%	100%	100%	100%	98.7%

For Protein,

- the overall exact match between the CM and the Proposed WM was 98.7% (592/600) with 95%CI: (97.4%; 99.3%),
- ≥ 96% of data points were within the ATE zone (green) for each color block
- 0% (0/600) of data points were within the LER (red) zone with 95%CI: (0.0%; 0.6%)

Combined Sites Results: pH

pH		pH CM													
		0 - 5.40	Near Cut-off 5.41– 5.60	5.61-6.15	Near Cut-off 6.16-6.34	6.35 - 6.65	Near Cut-off 6.66– 6.84	6.85-7.15	Near Cut-off 7.16 – 7.34	7.35-7.65	Near Cut-off 7.66 – 7.84	7.85-8.15	Near Cut-off 8.16 – 8.34	8.35 - 9.0	Total
Predicted Bins		5.0	5.0 or 6.0	6.0	6.0 or 6.5	6.5	6.5 or 7.0	7.0	7.0 or 7.5	7.5	7.5 or 8.0	8.0	8.0 or 8.5	8.5	
Uritek TC-201	5.0	76	14	3											93
	6.0	3	18	111	24	2									158
	6.5			1	9	57	24	2							93
	7.0						15	58	17	2					92
	7.5								5	54	16				75
	8.0										16	40	7		63
	8.5												9	17	26
Total		79	32	115	33	59	39	60	22	56	32	40	16	17	600
% Exact Match Agreement		96%	100%	97%	100%	97%	100%	97%	100%	96%	100%	100%	100%	100%	97.8%

For pH,

- the overall exact match between the CM and the Proposed WM was 97.8% (587/600) with 95%CI: (96.3%; 98.7%),
- ≥ 96% of data points were within the ATE zone (green) for each color block
- 0% (0/600) of data points were within the LER (red) zone with 95%CI: (0.0%; 0.6%)

Combined Sites Results: SPECIFIC GRAVITY

SG		Specific Gravity CM											
		≤1.005-1.006	Near Cutoff 1.007 – 1.008	1.009 - 1.011	Near Cutoff 1.012– 1.013	1.014-1.016	Near Cutoff 1.017 – 1.018	1.019 - 1.021	Near Cutoff 1.022 – 1.023	1.024 - 1.026	Near Cutoff 1.027 – 1.028	1.029 - ≥1.030	Total
Predicted Bins		1.005	1.005 or 1.010	1.010	1.010 or 1.015	1.015	1.015 or 1.020	1.020	1.020 or 1.025	1.025	1.025 or 1.030	1.030	
Uritek TC-201	1.005	150	24	1									175
	1.010	3	31	69	20	2							125
	1.015		1		24	61	17	1					104
	1.020						16	51	14				81
	1.025								12	48	6	1	67
	1.030									1	8	39	48
Total		153	56	70	44	63	33	52	26	49	14	40	600
% Exact Match Agreement		98%	98%	99%	100%	97%	100%	98%	100%	98%	100%	98%	98%

For Specific Gravity,

- the overall exact match between the CM and the Proposed WM was 98.3% (590/600) with 95%CI: (97.0%; 99.1%),
- ≥ 97% of data points were within the ATE zone (green) for each color block
- 0% (0/600) of data points were within the LER (red) zone with 95%CI: (0.0%; 0.6%)

Combined Sites Results: KETONES

KETONES		Ketones CM									
Semi-quantitative Bins		Neg, Neg	Trace, Neg	Trace, Trace	1+, Trace	1+, 1+	2+, 1+	2+, 2+	3+, 2+	3+, 3+	Total
Uritek TC-201	Neg	255	4	1							260
	Trace	5	5	55	2	1					68
	1+				3	60	2	1			66
	2+					1	7	63	5		76
	3+							1	2	38	41
Total		260	9	56	5	62	9	65	7	38	511
% Exact Match Agreement		98%	100%	98%	100%	97%	100%	97%	100%	100%	98.0%

For Ketones,

- the overall exact match between the CM and the Proposed WM was 98.0% (501/511) with 95%CI: (96.4%; 98.9%),
- ≥ 97% of data points were within the ATE zone (green) for each color block
- 0% (0/511) of data points were within the LER (red) zone with 95%CI: (0.0%; 0.7%)

Combined Sites Results: BLOOD

BLOOD		Blood CM									
Semi-quantitative Bins		Neg, Neg	Trace, Neg	Trace, Trace	1+, Trace	1+, 1+	2+, 1+	2+, 2+	3+, 2+	3+, 3+	Total
Uritek TC-201	Neg	218	7								225
	Trace	4	11	54	6						75
	1+			1	8	35	5	2			51
	2+						7	68	2	2	79
	3+							1	4	76	81
Total		222	18	55	14	35	12	71	6	78	511
% Exact Match Agreement		98%	100%	98%	100%	100%	100%	96%	100%	97%	98.0%

For Blood,

- the overall exact match between the CM and the Proposed WM was 98.0% (501/511) with 95%CI: (96.4%; 98.9%),
- ≥ 96% of data points were within the ATE zone (green) for each color block
- 0% (0/511) of data points were within the LER (red) zone with 95%CI: (0.0%; 0.7%)

Combined Sites Results: LEUKOCYTES

LEUKOCYTES		Leukocytes CM									
											Total
Semi-quantitative Bins		Neg, Neg	Trace, Neg	Trace, Trace	1+, Trace	1+, 1+	2+, 1+	2+, 2+	3+, 2+	3+, 3+	
Uritek TC-201	Neg	241	1								242
	Trace	2	12	29	4	1					48
	1+				8	53	5	3			69
	2+						7	79	8	1	95
	3+								4	53	57
Total		243	13	29	12	54	12	82	12	54	511
% Exact Match Agreement		99%	100%	100%	100%	98%	100%	96%	100%	98%	98.6%

For Leukocytes,

- the overall exact match between the CM and the Proposed WM was 98.6% (504/511) with 95%CI: (97.2%; 99.3%),
- ≥ 96% of data points were within the ATE zone (green) for each color block and
- 0% (0/511) of data points were within the LER (red) zone with 95%CI: (0.0%; 0.7%).

Combined Sites Results: UROBILINOGEN

UROBILINOGEN		Urobilinogen CM									
											Total
Semi-quantitative Bins		0.2, 0.2	1.0, 0.2	1.0, 1.0	2.0, 1.0	2.0, 2.0	4.0, 2.0	4.0, 4.0	8.0, 4.0	8.0, 8.0	
Uritek TC-201	0.2	374	4								378
	1.0	6	7	27							40
	2.0				4	24					28
	4.0						2	26			28
	8.0								4	33	37
Total		380	11	27	4	24	2	26	4	33	511
% Exact Match Agreement		98%	100%	100%	100%	100%	100%	100%	100%	100%	98.8%

For Urobilinogen,

- the overall exact match between the CM and the Proposed WM was 98.8% (505/511) with 95%CI: (97.5%; 99.5%),
- ≥ 98% of data points were within the ATE zone (green) for each color block and
- 0% (0/511) of data points were within the LER (red) zone with 95%CI: (0.0%; 0.7%).

Combined Sites Results: BILIRUBIN

BILIRUBIN		Bilirubin CM							
									Total
Semi-quantitative Bins		Neg, Neg	1+, Neg	1+, 1+	2+, 1+	2+, 2+	3+, 2+	3+, 3+	
Uritek TC-201	Neg	419	2						421
	1+	3	4	16	1				24
	2+					31			31
	3+						1	34	35
Total		422	6	16	1	31	1	34	511
% Exact Match Agreement		99%	100%	100%	100%	100%	100%	100%	99.4%

For Bilirubin,

- the overall exact match between the CM and the Proposed WM was 99.4% (508/511) with 95%CI: (98.3%; 99.8%),
- ≥ 99% of data points were within the ATE zone (green) for each color block
- 0% (0/511) of data points were within the LER (red) zone with 95%CI: (0.0%; 0.7%)

Combined Sites Results: NITRITE

NITRITE		Nitrite CM			
					Total
Qualitative Bins		Neg, Neg	Pos, Neg	Pos, Pos	
Uritek TC-201	Negative	357	10	0	367
	Positive	1	3	140	144
Total		358	13	140	511
% Exact Match Agreement		99.7%	100%	100%	99.8%

For Nitrite,

- the overall exact match between the CM and the Proposed WM was 99.80% (510/511) with 95%CI: (98.90%; 99.97%),
- ≥ 99.7% of data points were within the ATE zone (green) for each color block

3. Device performance with analyte concentration near the cutoff

A study was performed to determine the performance of the Uritek TC-201 Urine Chemistry Test System (proposed WM) at the concentration where each analyte changed from negative to the first positive color block. Samples were prepared by spiking the analytes to the following concentrations, C95 (weak positive) and C5 (weak negative) into negative urine for first positive color block. Each sample pool was later aliquoted into 60 sample tubes and distributed across the 3 clinical sites mentioned above (20 samples per site). These samples were analyzed by the same untrained operators who

participated in the method comparison study. The Detection Limit study performed in k160732 was used to determine the C95 (weak positive) and C5 (weak negative) concentrations for the first positive cutoff point (e.g., negative to trace/first positive) for each analyte. The weak positive (C95) and weak negative concentrations (C5) for each individual analyte and the percentage agreement at each corresponding color block is summarized in the table below:

Analyte	Color Block	Analyte Concentration	% Agreement
Glucose	Negative	C_5 – (b) (4) mg/dL	97%
	100 mg/dL	C_{95}- (b) (4) mg/dL	95%
Bilirubin	Negative	C_5 – (b) (4) mg/dL	100%
	Small	C_{95}- (b) (4) mg/dL	95%
Ketone	Negative	C_5 – (b) (4) mg/dL	100%
	Trace	C_{95}- (b) (4) mg/dL	97%
Blood	Negative	C_5 – (b) (4) Ery/µL	98%
	Trace	C_{95}- (b) (4) Ery/µL	95%
Protein	Negative	C_5 – (b) (4) mg/dL	100%
	Trace	C_{95}- (b) (4) mg/dL	95%
Nitrite	Negative	C_5 – (b) (4) mg/dL	97%
	Positive	C_{95}- (b) (4) mg/dL	95%
Leukocyte	Negative	C5 - (b) (4) ca cells/µL	100%
	Trace	C_{95}- (b) (4) ca cells/µL	95%
Urobilinogen	0.2 mg/dL	C_5 – (b) (4) EU/dL	100%
	1.0 mg/dL	C_{95}- (b) (4) EU/dL	98%
pH	6.5	C_5 – (b) (4)	95%
	7.0	C_{95}- (b) (4)	98%
SG	1.005	C_5 – (b) (4)	98%
	1.010	C_{95}- (b) (4)	97%

4. Operator Questionnaire

At the end of the study, the 18 untrained operators were given a questionnaire to assess the use of the Uritek TC-201. The questionnaire consisted of five questions, which asked the operators to rate the ease of use of the device on a scale from "very easy" (a score of 1) to "very hard" (a score of 10). Below is a summary table of the questions and scores for each question:

Questions	Score	
	1	2
1. Was the User Manual/Guide accompanying the Uritek TC-201 easy to understand?	78%	22%
2. Was the Package Insert accompanying the URS-10 strips easy to understand?	72%	28%
3. Was the device easy to use for the URS-10 test?	95%	5%
4. Were the test results easy to understand?	100%	-
5. Was it easy to know what to do if there was an error during testing based on the instructions on the device and included in the User Manual?	78%	22%

M. Labeling for Waived Devices

The labeling consists of:

1. Package Insert (Teco Diagnostics Urine Reagent (URS-10) Strips)
2. Operator's Manual (Uritek TC-201)
3. Quick Start Guide (Uritek TC-201)

The following elements are appropriately present:

- The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.
- The QSG is written at no higher than a 7th grade reading level and pictures and diagrams have been provided, as appropriate.
- The sections of the Operator's Manual intended for use by a CLIA waived operator are clearly marked as such and are written at no higher than a 7th grade reading level.
- The package insert and QSG identify the test as CLIA waived and contain a statement that a Certificate of Waiver is required to perform the test in a waived setting and contain information on how users can obtain a certificate.
- The package insert and QSG contain a statement that laboratories with a Certificate of Waiver must follow the manufacturer's instructions for performing the test. 42 CFR 493.15(e)(1)
- Instructions for quality control (QC) are integrated with procedural instructions for performing the test in the package insert, operator manual and QSG.

N. Conclusion:

The submitted information in this CLIA waiver application supports a CLIA waiver approval decision.