DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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November 17, 2014

SIEMENS HEALTHCARE DIAGNOSTICS, INC.
SUSAN TIBEDO
SR. MANAGER REGULATORY AFFAIRS
2 EDGEWATER DRIVE
NORWOOD MA 02062

Re: K140717
Trade/Device Name: CLINITEK Novus Automated Urine Chemistry Analyzer
CLINITEK Novus 10 Urinalysis Cassette,
CLINITEK Novus Calibration Kit
Regulation Number: 21 CFR 864.6550
Regulation Name: Occult Blood Test
Regulatory Class: II
Product Code: JIO, KQO, JJB, JIL, JIN, LJX, JMT, CEN, JIR, JRE, CDM, JIX
Dated: September 29, 2014
Received: October 1, 2014

Dear Ms. Susan Tibedo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the

electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney H. Lias -S

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
k140717

Device Name
CLINITEK Novus® Automated Urine Chemistry Analyzer
CLINITEK Novus® 10 Urinalysis Cassette
CLINITEK Novus® Calibration Kit

Indications for Use *(Describe)*

The CLINITEK Novus® Automated Urine Chemistry Analyzer is a fully automated urinalysis instrument. The CLINITEK Novus analyzer is intended to read Siemens Healthcare Diagnostics CLINITEK Novus Cassettes, as well as determine urine specific gravity and urine clarity. The CLINITEK Novus 10 Urinalysis Cassette is intended for the semi-quantitative measurement of the following parameters in urine: bilirubin, blood (occult), glucose, ketone (acetoacetic acid), leukocytes, nitrite (qualitative), pH, protein, color, and urobilinogen.

These measurements are used to assist diagnosis in the following areas:
- Carbohydrate metabolism (such as diabetes mellitus)
- Kidney function
- Liver function
- Metabolic disorders
- Urinary tract infection

For in vitro diagnostic use.

The CLINITEK Novus® Calibration Kit is intended to be used with the CLINITEK Novus Urinalysis Cassette to calibrate the CLINITEK Novus Automated Urine Chemistry analyzer. This product is for professional in vitro diagnostic use.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary (k140717)

This 510(k) summary is being submitted in accordance with the requirements of 21 CFR 807.92.

1.0 Submitter Information

Owner	Siemens Healthcare Diagnostics, Inc. 2 Edgewater Drive Norwood, MA 02062
Contact	Primary: Susan Tibedo Senior Manager Regulatory Affairs susan.tibedo@siemens.com 781-269-3888 TEL Secondary: Noor Malki VP, Clinical, Regulatory and Quality - POC 781-269-3401 TEL
Date Summary Prepared	November 12, 2014

2.0 Device Information

Proprietary Names	CLINITEK Novus® Automated Urine Chemistry Analyzer CLINITEK Novus® 10 Urinalysis Cassette CLINITEK Novus® Calibration Kit
Common Name	Automated Urine Chemistry Analyzer
Main Classification Name	Automated urinalysis system 21 CFR 862.2900, Class I Product Code KQO

Subsequent Classifications

Classification				
Device	***Regulation Section***	***Device Class***	***Product Code***	***Test***
Automated urinalysis system	21 CFR 862.2900	1	KQO	Automated Urine Chemistry Analyzer
Bilirubin	21 CFR 862.1115	1	JJB	Urinary bilirubin and its conjugates (non-quantitative) test system
Blood (occult)	21 CFR 864.6550	2	JIO	Occult blood test
Glucose	21 CFR 862.1340	2	JIL	Urinary glucose (non-quantitative) test system
Ketone (acetoacetic acid)	21 CFR 862.1435	1	JIN	Ketones (non-quantitative) test system
Leukocytes	21 CFR 864.7675	1	LJX	Leukocyte peroxidase test

Classification				
Device	***Regulation Section***	***Device Class***	***Product Code***	***Test***
Nitrite	21 CFR 862.1510	1	JMT	Nitrite (non-quantitative) test system
pH	21 CFR 862.1550	1	CEN	Urinary pH (nonquantitative) test system
Protein	21 CFR 862.1645	1	JIR	Urinary protein or albumin (non-quantitative) test system
Specific gravity	21 CFR 862.2800	1	JRE	Refractometer for clinical use
Urobilinogen	21 CFR 862.1785	1	CDM	Urinary urobilinogen (non-quantitative) test system
Calibrator	21 CFR 862.1150	2	JIX	Calibrator, multi-analyte mixture

3.0 Predicate Device

	Predicate
Device Name	CLINITEK Atlas
Common Name	Automated Urine Chemistry Analyzer
510(k) Number	K932674
Manufacturer	Siemens Healthcare Diagnostics

4.0 Device Description

The CLINITEK Novus® system is a fully automated urine chemistry analyzer that is designed for use with the CLINITEK Novus® 10 Urinalysis Cassette. The analyzer automates the process of urine strip testing by dispensing urine samples onto a test pad, and then by reading the color and intensity of light reflected from the reacted test pads, converts the results into clinically meaningful units.

Test results from the test pads are qualitative and semi-quantitative; specific gravity is measured by a refractometer assembly.

Analyte	***Abbreviation***	***Conventional Semi-Quantitative***	***SI Semi-Quantitative***	***Qualitative***
Bilirubin	**BIL**	Negative	Negative	Negative
		Small	Small	1+
		Moderate	Moderate	2+
		Large	Large	3+

Analyte	*Abbreviation*	*Conventional Semi-Quantitative*	*SI Semi-Quantitative*	*Qualitative*
Blood	**BLO**	Negative	Negative	Negative
		Trace	Trace	Trace
		NHT	NHT	NHT
		Small	Small	1+
		Moderate	Moderate	2+
		Large	Large	3+
Glucose	**GLU**	Negative	Negative	Negative
		100 mg/dL	5.5 mmol/L	Trace
		250 mg/dL	14 mmol/L	1+
		500 mg/dL	28 mmol/L	2+
		1000 mg/dL	>=55 mmol/L	3+
Ketone	**KET**	Negative	Negative	Negative
		Trace	Trace	Trace
		15 mg/dL	1.5 mmol/L	1+
		40 mg/dL	3.9 mmol/L	2+
		80 mg/dL	7.8 mmol/L	3+
		>=160 mg/dL	>=15.6 mmol/L	4+
Leukocyte	**LEU**	Negative	Negative	Negative
		Trace	Ca 15 cells/µL	Trace
		Small	Ca 70 cells/µL	1+
		Moderate	Ca 125 cells/µL	2+
		Large	Ca 500 cells/µL	3+
Nitrite	**NIT**	Negative	Negative	Negative
		Positive	Positive	Positive
pH	**pH**	5.0	5.0	5.0
		5.5	5.5	5.5
		6.0	6.0	6.0
		6.5	6.5	6.5
		7.0	7.0	7.0
		7.5	7.5	7.5
		8.0	8.0	8.0
		8.5	8.5	8.5
		>=9.0	>=9.0	>=9.0

Analyte	*Abbreviation*	*Conventional Semi-Quantitative*	*SI Semi-Quantitative*	*Qualitative*
Protein	**PRO**	Negative	Negative	Negative
		Trace	Trace	Trace
		30 mg/dL	0.3 g/L	1+
		100 mg/dL	1.0 g/L	2+
		300 mg/dL	3.0 g/L	3+
		>=1000 mg/dL	>=10.0 g/L	4+
Specific Gravity (0.005 units)	**SG**	<=1.005	<=1.005	<=1.005
		1.010	1.010	1.010
		1.015	1.015	1.015
		1.020	1.020	1.020
		1.025	1.025	1.025
		>=1.030	>=1.030	>=1.030
Specific Gravity (0.001 units)	**SG**	1.000 to <=1.099 in increments of 0.001		
Urobilinogen	**URO UBG (SI)**	0.2 E.U./dL (mg/dL)	3.2 µmol/L	0.2 E.U./dL
		1 E.U./dL	16 µmol/L	1 E.U./dL
		2 E.U./dL	33 µmol/L	2 E.U./dL
		4 E.U./dL	66 µmol/L	4 E.U./dL
		>=8 E.U./dL	>=131µmol/L	>=8 E.U./dL
Color	**COL**	Yellow	Yellow	Yellow
		Dark Yellow	Dark Yellow	Dark Yellow
		Orange	Orange	Orange
		Red	Red	Red
		Green	Green	Green
		Other	Other	Other
Clarity	**CLA**	Clear	Clear	Clear
		Cloudy	Cloudy	Cloudy
		Turbid	Turbid	Turbid
		Sl. Cloudy	Sl. Cloudy	Sl. Cloudy

5.0 Intended Use Statement

The CLINITEK Novus® Automated Urine Chemistry Analyzer is a fully automated urinalysis instrument for clinical laboratory use. The CLINITEK Novus analyzer is intended to read Siemens Healthcare Diagnostics CLINITEK Novus Cassettes, as well as determine urine specific gravity and urine clarity.

The CLINITEK Novus 10 Urinalysis Cassette is intended for the semi-quantitative measurement of the following parameters in urine: bilirubin, blood (occult), glucose, ketone (acetoacetic acid), leukocytes, nitrite (qualitative), pH, protein, color, and urobilinogen.

These measurements are used to assist diagnosis in the following areas:

- Carbohydrate metabolism (such as diabetes mellitus)
- Kidney function
- Liver function
- Metabolic disorders
- Urinary tract infection

For *in vitro* diagnostic use.

The CLINITEK Novus® Calibration Kit is intended to be used with the CLINITEK Novus Urinalysis Cassette to calibrate the CLINITEK Novus Automated Urine Chemistry Analyzer. This product is for professional *in vitro* diagnostic use.

6.0 Summary Comparison of Technological Characteristics

	Feature	**Candidate Device** **CLINITEK Novus analyzer**	**Predicate Device** **CLINITEK Atlas analyzer**
	Intended Use	Automated Urine Chemistry Analyzer intended for professional *in vitro* diagnostic use in clinical laboratories. The analyzer is intended for the measurement of the following components in urine: bilirubin, blood (occult), glucose, ketone (acetoacetic acid), leukocytes, nitrite, pH, protein, urobilinogen and specific gravity.	Same
	Urinalysis Strips Analytical Method	Light is reflected at specific wavelengths from the test pad “read area”. Reported results depend upon the degree of color change and intensity in the pad which is directly related to the concentration of the analyte in the urine.	Same

6.0 Summary Comparison of Technological Characteristics

Feature	Candidate Device CLINITEK Novus analyzer	Predicate Device CLINITEK Atlas analyzer
Specific Gravity	Fiber optic refractive index method.	Same
Instrument Optical System	Two pairs of LEDs illuminate the test pads and a camera in the analyzer electronically analyzes the color and intensity of the light reflected from the reacted test pads.	Reflectance photometer consisting of halogen lamp, fiber optics and lens and detector. Light travels onto a lens where it is focused onto the detector, and the intensity is converted into electrical impulses to generate clinically meaningful units.
Reagent Format	Cassette contains reagent test pads organized in strips on a test card format.	Roll containing reagent test pads in strip format.
Reagent Test Pad Chemistry	Each reagent test pad consists of impregnated paper with chemicals specific to measuring the analyte.	Same
Reagent Storage and Stability	Storage temperature: 15–30°C Shelf life: 12 months Open shelf life: 14 days	Same
Calibration Method	The system performs a cleaning cycle and dry pad calibration. Four, liquid, ready-to-use calibrators are used to calibrate the SG sensor and certain test pads.	Same without dry pad calibration
Quality Check	Conducts a quality check to assess if the test pad has been exposed to high humidity.	None
Data Storage	7,500 Patient results 200 Calibration results 400 Quality control results	1000 Patient results 200 QC / calibrator results
Connectivity	LIS, HIS and remote-diagnosis ready. Optional module enables hospital network (such as HIS/LIS) connectivity. This also allows copying a selected setup across multiple instruments via the network.	Same
Barcode	Internal barcode reader Optional handheld barcode reader – automatic entry of control lot and expiration	Same
User Interface	Integrated color touch screen	Keypad and 12-line display

Calibrators

Similarities and Differences

Feature	Candidate Device CLINITEK Novus Calibration Kit	Predicate Device CLINITEK Atlas Calibration Kit (k932674)
Intended Use	In vitro diagnostic product for the calibration of CLINITEK Automated Urine Chemistry Analyzer	Same
Preparation	Ready to use	Same
Matrix	Liquid	Same
Number of calibrators	Four: Calibrator #1, #2, #3 and #4	Same
Cleaning cycle	Includes a cleaning cycle before calibration	Does not include a cleaning cycle before calibration
Stability	Shelf-life: 18 months stored at 2–8°C Open bottle: 18 months stored at 2–8°C	Same
Traceability	Calibrators have been tested using materials or calibrated devices which are traceable to the National Institute of Standards and Technology in conformance with standard EN 17511:2001.	Same
Value Assignment	Calibrators are prepared to achieve targeted analyte values. The calibrators have fixed values and are not lot specific. Calibrators must meet internal specifications before release.	Same

7.0 Test Principle

The CLINITEK Novus analyzer utilizes an optical system that has a digital imager. The concentration of each analyte is measured by the color change that develops when a sample is deposited on a test pad. The imager records the color and intensity of the light reflected off the reacted tested pads, which are illuminated by two pairs of LED lights. The optical system converts this data into clinically meaningful results.

Specific gravity (SG) is determined by the fiber optic refractive index method. The SG sensor measures the amount of light passing through the fiber optic at one end. Because the refractive index is proportional to specific gravity, the light measured correlates to the specific gravity of the sample yielding a quantitative result.

8.0 Performance Characteristics

Analytical Performance

a. Precision / Reproducibility

Precision was evaluated on 3 CLINITEK Novus analyzers over 10 days of testing. Two runs per day were completed with 2 replicates per run across 1 lot of CLINITEK Novus reagent urinalysis cassettes. Commercially available controls were used providing a high positive control, a low clinically significant positive control and a negative control for evaluating the percent agreement. The results are shown in the following tables:

Table 1. Reproducibility (Within Device) for Low / Negative Control

Analyte	Control Limits	Exact Block Agreement (%)	Agreement within ±1 Block (%)
Bilirubin	Negative	120/120 (100%)	120/120 (100%)
Blood	Negative	119/120 (99.2%)	120/120 (100%)
Glucose	Negative	120/120 (100%)	120/120 (100%)
Ketone	Negative	120/120 (100%)	120/120 (100%)
Leukocyte	Negative	120/120 (100%)	120/120 (100%)
Nitrite	Negative	120/120 (100%)	120/120 (100%)
pH	< 6.5	120/120 (100%)	120/120 (100%)
Protein	Negative	120/120 (100%)	120/120 (100%)
SG	< 1.005	120/120 (100%)	120/120 (100%)
Urobilinogen	< 1.0 mg/dL	114/120 (95%)	120/120 (100%)

Table 2. Reproducibility (Within Device) for Low Positive Control

Analyte	Control Limits	Exact Block Agreement	Agreement within ±1 Block
Bilirubin	Moderate	120/120 (100%)	120/120 (100%)
Blood	Trace	120/120 (100%)	120/120 (100%)
Glucose	100 mg/dL	119/120 (99.2%)	120/120 (100%)
Ketone	15 mg/dL	120/120 (100%)	120/120 (100%)
Leukocyte	Small	109/120 (90.8%)	120/120 (100%)
pH	7.0-8.0	120/120 (100%)	120/120 (100%)
Protein	30 mg/dL	120/120 (100%)	120/120 (100%)
SG	1.006 – 1.019	120/120 (100%)	120/120 (100%)
Urobilinogen	2 mg/dL	120/120 (100%)	120/120 (100%)

Table 3. Reproducibility (Within Device) High Positive Control

Analyte	Control Limits	Exact Block Agreement	Agreement within ±1 Block
Bilirubin	Large	120/120 (100%)	120/120 (100%)
Blood	Large	120/120 (100%)	120/120 (100%)
Glucose	1000 mg/dL	117/120 (97.5%)	120/120 (100%)
Ketone	80 mg/dL	108/120 (90%)	120/120 (100%)
Leukocyte	Large	120/120 (100%)	120/120 (100%)
Nitrite	Positive	120/120 (100%)	120/120 (100%)

Table 3. Reproducibility (Within Device) High Positive Control

Analyte	Control Limits	Exact Block Agreement	Agreement within ±1 Block
pH	>9.0	120/120 (100%)	120/120 (100%)
Protein	300 mg/dL	120/120 (100%)	120/120 (100%)
SG	>/= 1.020	120/120 (100%)	120/120 (100%)
Urobilinogen	4 mg/dL	115/120 (95.8%)	120/120 (100%)

b. Detection Limit

The sensitivity of the CLINITEK Novus urinalysis cassette reagents was evaluated by spiking negative pooled human urine with known quantity of analytes. The analytes were spiked at multiple concentrations around the transition value from negative to positive. Multiple samples were tested at each concentration on the CLINITEK Novus analyzer. Sensitivity was defined as the concentration in which ≥ 55% of the results were positive. The lower limits of analyte detection for each reagent test are shown in the following table:

Analyte	Limit of Detection (Sensitivity)
Bilirubin	0.5 mg/dL
Blood	0.013 mg/dL
Glucose	36 mg/dL
Ketone	3.6 mg/dL
Leukocyte	6.0 cells/µL
Nitrite	0.06 mg/dL
Protein	10.8 mg/dL
Urobilinogen	0.24 mg/dL

c. Analytical Specificity

Urine samples were spiked with a high concentration of potentially interfering substances. Substances that resulted in a change in the reported clinical block output were serially diluted to determine the concentration at which the substance interfered. The results are in the following table:

Results for Effect of Potentially Interfering Substances at the Lowest Concentration

Interfering Substance	Initial Conc Tested	BIL	BLO	GLU	KET	LEU	NIT	PRO	URO
Acetaminophen	40 mg/dL	None	None	None	None	None	None	None	None
Acetylcysteine	270 mg/dL	False Negative at 135 mg/dL	False Negative at 67.5 mg/dL	False Negative at 67.5 mg/dL	False Positive at 67.5 mg/dL	None	None	None	False Negative at 67.5 mg/dL
Ascorbic Acid	100 mg/dL	False Negative at 25 mg/dL	False Negative at 25 mg/dL	False Negative at 25 mg/dL	None	None	False Negative at 100 mg/dL	None	None
Ammonium Chloride	200 mg/dL	None	None	None	None	None	None	None	None
Boric Acid	1000 mg/dL	None	None	None	False Negative at 500 mg/dL	None	None	None	None
Calcium Chloride	100 mg/dL	None	None	None	None	False Negative at 100 mg/dL	None	None	None
Captopril	50 mg/dL	None	False Negative at 12.5 mg/dL	None	False Positive at 12.5 mg/dL	None	None	None	False Negative at 25 mg/dL
Cefoxitin	66 mg/dL	None	None	None	None	None	None	None	None
Cephalosporin	80 mg/dL	None	None	None	None	None	None	None	None
Chlorhexidine	150 mg/dL	None	False Negative at 112.5 mg/dL	None	None	False Negative at 37.5 mg/dL	None	False Positive at 37.5 mg/dL	False Negative at 75 mg/dL
Chloroquine	40 mg/dL	None	False Negative at 40 mg/dL	None	None	False Negative at 20 mg/dL	None	False Positive at 20 mg/dL	None

Results for Effect of Potentially Interfering Substances at the Lowest Concentration

Interfering Substance	Initial Conc Tested	BIL	BLO	GLU	KET	LEU	NIT	PRO	URO
Citric Acid	80 mg/dL	False Negative at 40 mg/dL	None	None	None	None	None	None	None
Curcuma	300 mg/dL	False Negative at 75 mg/dL	False Negative at 75 mg/dL	None	False Positive at 75 mg/dL	False Positive at 75 mg/dL	False Positive at 75 mg/dL	None	False Negative /Positive at 75 mg/dL
Formalin	370 mg/dL	None	False Negative at 185 mg/dL	None	False Negative at 92.5 mg/dL	False Positive at 92.5 mg/dL	False Negative at 185 mg/dL	None	False Negative at 92.5 mg/dL
Galactose	20 mg/dL	None	None	None	None	None	None	None	None
Gentamicin Sulfate	6 mg/dL	None	None	None	None	None	None	None	None
Glucose	5 g/dL	None	None	NA	None	False Negative at 1250 mg/dL	None	None	False Negative at 2500 mg/dL
Glycine	400 mg/dL	None	None	None	None	None	None	None	None
Glyburide	15 ug/mL	None	None	None	None	None	None	None	None
Hemoglobin	5 mg/dL	None	None	None	None	None	None	None	None
Hypochlorite	2.60%	False Negative at 1.3%	False Positive at 0.65%	False Positive at 1.3%	False Negative at 1.3%	False Negative at 0.65%	None	None	False Negative at 0.65%
Hydrochloro-thiazide	6 mg/mL	None	None	None	None	None	None	None	False Negative at 6 mg/dL
Indican	50 mg/dL	None	None	None	None	None	None	None	None
Imipenem	100 mg/dL	None	None	None	False Positive at 50 mg/dL	None	None	None	None

Results for Effect of Potentially Interfering Substances at the Lowest Concentration

Interfering Substance	Initial Conc Tested	BIL	BLO	GLU	KET	LEU	NIT	PRO	URO
Keflex	150 mg/dL	None	None	None	None	None	None	None	None
Keflin	50 mg/dL	None	None	None	None	None	None	None	None
Lactose	20 mg/dL	None	None	None	None	None	None	None	False Negative at 20 mg/dL
Levadopa	75 mg/dL	None	False Negative at 18.8 mg/dL	None	False Positive at 56 mg/dL	None	None	None	None
Lodine	100 mg/dL	None	None	None	None	None	None	None	None
Meropenem	100 mg/dL	None	None	None	None	None	None	None	False Negative at 100 mg/dL
Mesna	80 mg/dL	False Negative at 20 mg/dL	False Negative at 20 mg/dL	False Negative at 20 mg/dL	False Positive at 20 mg/dL	None	None	None	False Negative at 20 mg/dL
Metformin	4 mg/mL	None	None	None	None	None	None	None	None
Nitrofurantoin	120 mg/dL	None	None	None	None	None	None	None	False Negative at 120 mg/dL
Oxalic Acid	95 mg/dL	None	None	None	None	None	False Negative at 71 mg/dL	None	None
P-aminosalicyclic acid	250 mg/dL	None	None	None	None	None	None	None	False Negative at 62.5 mg/dL
Penicillin	300 mg/dL	None	None	None	None	None	None	None	None
Pyridium	200 mg/dL	None	None	None	None	None	False Positive at 50 mg/dL	False Positive at 150 mg/dL	False Positive at 100 mg/dL

Results for Effect of Potentially Interfering Substances at the Lowest Concentration

Interfering Substance	Initial Conc Tested	BIL	BLO	GLU	KET	LEU	NIT	PRO	URO
Potassium Chloride	1200 mg/dL	None	None	None	None	None	None	None	None
Quinidine	30 mg/dL	None	None	None	None	None	None	None	None
Riboflavin	120 mg/dL	None	None	None	None	None	False Positive at 30 mg/dL	None	None
Sodium Nitrite	3 mg/dL	None	None	None	None	None	NA	None	None
Sulfamethoxazole	70 mg/dL	None	None	None	None	None	None	None	False Negative at 17.5 mg/dL
Tagamet	10 mg/dL	None	None	None	None	None	None	None	False Negative at 5 mg/dL
Tetracycline	12 mg/dL	None	None	None	None	None	None	None	None
pH > 9	NA	None	None	None	None	None	None	None	None
Microbial Peroxidase	NA	None	False Positive	None	None	None	None	None	None

Comparison Studies

d. Method Comparison with Predicate Device

The method comparison study compared the clinical results of the CLINITEK Novus analyzer to the predicate device. The study was conducted across 3 sites with up to 2773 specimens tested. The results for overall percent agreement and within one level agreement met acceptance criteria. In the following tables, results are shown for all sites combined.

BIL		Predicate Result			
		Negative	Small	Moderate	Large
CLINITEK Novus Result	Negative	2234	104	1	1
	Small	5	190	15	1
	Moderate		1	112	7
	Large				102
Total		2239	295	128	111
% exact match		99.8%	64.4%	87.5%	91.9%
% within 1 block		100.0%	100.0%	99.2%	98.2%

BLO		Predicate Result				
		Negative	Trace	Small	Moderate	Large
CLINITEK Novus Result	Negative	1489	4	1		
	Trace/NHT	34	97	12		
	Small		18	127	10	
	Moderate			5	125	14
	Large				1	204
Total		1523	119	145	136	218
% exact match		97.8%	81.5%	87.6%	91.9%	93.6%
% within 1 block		100.0%	100.0%	99.7%	100.0%	100.0%

GLU		Predicate Result				
		Negative	100 mg/dL	250 mg/dL	500 mg/dL	1000 mg/dL
CLINITEK Novus Result	Negative	1563				
	100 mg/dL	7	147			
	250 mg/dL		19	95		
	500 mg/dL			8	88	4
	1000 mg/dL				4	183
Total		1570	166	103	92	187
% exact match		99.6%	88.5%	92.2%	95.7%	97.9%
% within 1 block		100.0%	100.0%	100.0%	100.0%	100.0%

KET		Predicate Result					
		Negative	Trace	15 mg/dL	40 mg/dL	80 mg/dL	160 mg/dL
CLINITEK Novus Result	Negative	1670	14		1*		
	Trace	2	158	9			
	15 mg/dL		2	82	6		
	40 mg/dL			2	117	1	
	80 mg/dL					66	
	160 mg/dL					5	28
Total		1672	174	93	124	72	28
% exact match		99.9%	90.8%	88.2%	94.4%	91.7%	100.0%
% within 1 block		100.0%	100.0%	100.0%	99.2%	100.0%	100.0%

* This is a highly colored sample. Predicate labeling cautions testing of highly colored samples as they may yield a falsely elevated result.

LEU		CLINITEK Atlas Result				
		Negative	Trace	Small	Moderate	Large
CLINITEK Novus Result	Negative	1600	5	1		
	Trace	79	80	13		
	Small	1	10	129	3	
	Moderate			16	85	5
	Large				6	157
Total		1680	95	159	94	162
% exact match		95.0%	85.7%	81.1%	90.4%	96.6%
% within 1 block		99.9%	100.0%	99.7%	100.0%	100.0%

NIT		Predicate Result	
		Negative	Positive
CLINITEK Novus Result	Negative	1707	
	Positive	12	399
Total		1719	399
% exact match		99.3%	100.0%
% within 1 block		100.0%	100.0%

pH*		Predicate Result							
		5	5.5	6	6.5	7	7.5	8	8.5
CLINITEK Novus Result	5	85	121						
	5.5	1	203	213					
	6		1	426	19				
	6.5			26	399	10			
	7				33	376	2		
	7.5					106	178		
	8			1			64	44	1
	8.5						1	51	49
	>=9.0							2	361
Total		86	325	666	451	492	245	97	411
% exact match		98.8%	62.5%	64.0%	88.5%	76.4%	72.7%	45.4%	99.8%
% within 1 block		100.0%	100.0%	99.9%	100.0%	100.0%	99.6%	97.5%	100.0%

*Results on CLINITEK Novus of ≥8.5 were considered a match to a pH of 8.5 on the predicate.

PRO		Predicate Result					
		Negative	Trace	30 mg/dL	100 mg/dL	300 mg/dL	1000 mg/dL
CLINITEK Novus Result	Negative	1511	2				
	Trace	24	207	4			
	30 mg/dL		20	184	3		
	100 mg/dL	1		7	145	1	
	300 mg/dL				7	77	8
	1000 mg/dL						71
Total		1536	229	195	155	78	79
% exact match		98.4%	90.4%	94.4%	93.5%	98.7%	89.9%
% within 1 block		99.9%	100.0%	100.0%	100.0%	100.0%	100.0%

URO		Predicate Result				
		0.2 mg/dL	1 mg/dL	2 mg/dL	4 mg/dL	8mg/dL
CLINITEK Novus Result	0.2 mg/dL	1982	53			
	1 mg/dL	2	327	15		
	2 mg/dL		2	209	10	
	4 mg/dL			5	116	3
	8 mg/dL				4	45
Total		1984	382	229	130	48
% exact match		99.9%	85.6%	91.3%	89.2%	93.8%
% within 1 block		100.0%	100.0%	100.0%	100.0%	100.0%

As the number of contrived samples for URO exceeded 15%, testing was also performed at a fourth site. For this fourth site, less than 5% of the samples were contrived. Results are in the following table:

URO		Predicate Result				
		0.2 mg/dL	1 mg/dL	2 mg/dL	4 mg/dL	8 mg/dL
CLINITEK Novus Result	0.2 mg/dL	187	2			
	1 mg/dL		46			
	2 mg/dL			10		
	4 mg/dL				12	
	8 mg/dL					4
Total		187	48	10	12	4
% exact match		100.0%	95.8%	100.0%	100.0%	100.0%
% within 1 level		100.0%	100.0%	100.0%	100.0%	100.0%

Overall Specific Gravity Slope and Intercept

Site	N	R^2	Slope	Intercept
Overall	1993	0.983	1.020	-0.019

c. Matrix Comparison

Not applicable. The device is for urine samples only.

Clinical Studies

a. Clinical Sensitivity

Not applicable

b. Clinical Specificity

Not applicable

Clinical Cut-off

Not applicable

Expected Values / Reference Range

Complete details of the expected analyte values are provided in the labeling.

9.0 Instrument Name:

CLINITEK Novus Automated Urine Chemistry Analyzer

10.0 System Descriptions

Modes of Operation

Single and continuous testing.

Specimen Identification

An internal barcode reader scans the barcode labels on the sample tubes in the racks or sample identification may be entered manually using the touch screen keyboard.

Specimen Sampling and Handling

The CLINITEK Novus system can analyze multiple samples. The sample pipette aspirates a sample from the sample tube and dispenses sample onto each test pad.

Calibration

The CLINITEK Novus system uses four liquid calibration solutions to perform a calibration reflectance check. The calibrators have a fixed value with no lot specific values. A calibration must be performed when a new lot of reagent cassette is loaded onto the system or a new cassette of the same lot is loaded and the calibration is older than 24 hours.

The calibrators are identical to those cleared in K932674.

Quality Control

Recommendations for testing quality control are in the labeling. Routinely test at least 2 levels (negative/low and positive) of an appropriate commercially available control to confirm performance of the CLINITEK Novus urinalysis cassette. Controls may also be randomly placed in each batch of samples tested. Each laboratory should establish its own goals for acceptable standards of performance, and should question handling and testing procedures if these standards are not met.

The CLINITEK Atlas controls, cleared in K932674, may be used with the CLINITEK Novus automated urine chemistry analyzer.

Other Supportive Instrument Performance Characteristics Data Not Covered in the "Performance Characteristics" Section above:

None

11.0 Conclusion

The results of these studies demonstrate that the CLINITEK Novus automated urine chemistry analyzer and CLINITEK Novus 10 urinalysis cassette is similar to the predicate in both Technological Characteristics and Intended Use. The data presented is a summary of external clinical evaluation, internal laboratory evaluation, and software development information. The CLINITEK Novus performance was shown to be substantially equivalent to the predicate urinalysis device.