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

A. 510(k) Number:

k101852

B. Purpose for Submission:

New Device

C. Measurand:

Urine tests for: Glucose, Occult Blood, Urobilinogen, pH, Nitrite, Specific Gravity, Leukocytes, Ascorbic Acid, Ketones, Protein, and Bilirubin

D. Type of Test:

Qualitative and semi-quantitative

E. Applicant:

Iris Diagnostics

F. Proprietary and Established Names:

iChem®VELOCITY™ Automated Urine Chemistry System

iChem®VELOCITY™ Chemistry Strips.

iChem®VELOCITY™ Cal Chek Kit

G. Regulatory Information:

1. Regulation section:

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

test system			
Ketones (non-quantitative test system)	JIN	I	21 CFR§862.1435
Urinary protein or albumin (non-quantitative) test system	JIR	I	21 CFR§862.1645
Nitrite (non-quantitative) test system	JMT	I	21 CFR§862.1510
Leukocyte peroxidase test	LJX	I	21 CFR§864.7675
Urinary pH (non-quantitative) test system	CEN	I	21 CFR§862.1550
Refractometer for Clinical Use	JRE	I	21 CFR§862.2800
Ascorbic Acid Test System	JMA	I	21 CFR§862.1095
Automated Urinalysis System	KQO	I	21 CFR§862.2900

4. Panel:

   (75) Clinical Chemistry and (81) Hematology

H. Intended Use:

1. Intended use(s):

   See indications for use below.

2. Indication(s) for use:

   The iChem®VELOCITY™ automated urine chemistry system is an in vitro diagnostic device used to automate the urine chemistry analysis profile using iChem®VELOCITY™ Urine Chemistry Strips. The iChem ®VELOCITY™ can be used as a stand alone-system, as well as in an iQ®200 Series system, a configuration given the proprietary name iRICELL™ as it is designed to be hardware and software compatible with iQ200 Series systems. It produces quantitative results for specific gravity, semi-quantitative results for glucose, blood, leukocyte esterase, bilirubin, urobilinogen, pH, protein, ketones and ascorbic acid; and qualitative results for nitrites, color and clarity. iChem®VELOCITY™ strips are intended for use only with the iChem®VELOCITY™ analyzer. In particular they are not intended for visual reading. The iChem® VELOCITY™ test strips are not intended for visual reading. The iChem®VELOCITY™ is not intended to be used as a Point of Care (POC) analyzer.

   These measurements are used to aid in the diagnosis of metabolic disorders, kidney function anomalies, urinary tract infections, and liver function. Tests performed using the iChem® VELOCITY™ are intended for clinical laboratory use and in vitro diagnostic use only.

iChem® VELOCITY ™ CalChek Kit

iChem ®VELOCITY™ CalChek Kit is a set of assayed and unassayed *in vitro* diagnostic controls for monitoring performance of the iChem ®VELOCITY ™ urine chemistry analyzer.

The controls include assayed liquid controls for the monitoring of the specific gravity measurement module, and unassayed liquid color and clarity controls for the monitoring of color and clarity measurements. The kit also includes a set of assayed reflectance strips for the monitoring of reflectance measurements. These measurements monitored by these controls are part of an automated urine chemistry analyzer 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):

   Prescription use only

4. Special instrument requirements:

   iChem® VELOCITY™ automated urine chemistry system

I. Device Description:

The iChem® VELOCITY™ is a fully automated, computer-controlled urine chemistry analyzer intended for use only with the iChem® VELOCITY ™ Chemistry strips for the measurement of ten urine chemistry analytes from the chemistry strip plus the measurement of specific gravity using an electronic refractometer assembly and the qualitative measurement of color and clarity by optical absorbance and scattering methods. A Cal Check kit is included that contains SG Calchek, Color CalCheks and Clarity CalCheks in a liquid ready to use form.

J. Substantial Equivalence Information:

1. Predicate device name(s):
   iChem 100 Analyzer 10SG strips
   IRISSpec Gravity Control™ 1, 2 and Arkray Check Strips

2. Predicate 510(k) number(s):
   k060280
   k013783

3. Comparison with predicate:

Similarities and Differences		
Item	iChem VELOCITY Urine Chemistry system (Proposed Device)	iChem 100 Analyzer and 10SG strips (k060280) (Predicate Device)
Intended Use	Intended for the *in vitro* measurement of multiple analytes	Same
Anaylzer	Automated urine analyzer	Semi-automated urine analyzer
Analyte	specific gravity, glucose, blood, leukocyte esterase, bilirubin, urobilinogen, pH, protein, ketones and ascorbic acid, nitrites, color and clarity	glucose (GLU), Protein (PRO), bilirubin (BIL), urobilinogen (URO), pH, blood (BLD), ketones (KET), nitrite (NIT), leukocytes (LEU), specific gravity (SG) and color
Specimen	Urine	Same
Chemistry Strips	For use with iChem Velocity test strips only	For use with IChem 10 SG multi-parameter test strips
Design	Uses fixed-time end-point reflectance for all chemistry determinations.	Same

Similarities and Differences		
Item	iChem VELOCITY Calchek Kit (Proposed Device)	IRISSpec Gravity Control1™ and IRISSpec Gravity Control 2 ™ k013783
Intended Use	Assayed and Unassayed QC materials for monitoring of urine chemistry specific gravity, color and clarity measurements. The kit also includes a set of assayed reflectance strips for the monitoring of reflectance measurements on the iChem VELOCITY Urine Analyzer.	Same
Analytes	Specific Gravity at three levels	Specific Gravity at two levels
Usage	Vial is intended for one time use only.	Contents dispensed for multiple uses.
Packaging-container	10 mL Vacutainers	500 mL glass container
Form	Liquid, ready to use	Same
Composition	Glycerol, salts, food dyes, preservatives, dissolved in deionized water. No biological material.	Salts, food coloring, glycerin, stabilizers, preservative in deionized

Similarities and Differences		
Item	iChem VELOCITY Calchek Kit (Proposed Device)	IRISSpec Gravity Control1™ and IRISSpec Gravity Control 2 ™ k013783
		water.
Storage	20-28˚C	Dark, dry place (2-8˚C)
Stability	Open Vial Stability: Single one time use. Closed Vial stability: 1 year	Open Vial Stability: 30 days. Closed Vial stability: 1 year

Item	IRIS Reflectance CalCheks (Proposed Device)	Arkray Check Strips (k013783)
Composition	Munsell paper of various reflectances laminated by mylar foil.	One plain mylar foil, one laminate.
Reflectance acceptance ranges	Programmed into instrument	Same
Reusable	No	Yes, until results are out of range
Shelf-life	1 year	Not specified
Storage Temperature	18-25˚C	20-28˚C

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

CEN 13640 Stability Testing of In Vitro Diagnostic Reagents; 2002

EP12-A2 User Protocol for Evaluation of Qualitative Test Performance; January 2008

EP7-A2 Interference Testing in Clinical Chemistry

L. Test Principle:

The iChem® VELOCITY ™ is an automatic chemistry system performing measurements of urine and chemical constituents utilizing test strips read by wavelength reflectance and specific gravity using the refractive index.

Reflectance photometry analyzes the intensity and color of light reflected from the reagent areas of a urinalysis test strip. Using three LEDs and one black and white complementary metal oxide semiconductor camera (CMOS), the optical system reads the color change in the urine strips after a sample is applied.

The measurement of the ten analytes on the iChem® VELOCITY™ chemistry strip is based on optical measurement of percent reflectance of visible light flashed on reagent pads that undergo a color development reaction proportional to the analyte concentration. The sensor is a complementary metal-oxide semiconductor (CMOS) digital camera assembly.

Glucose-Two step enzymatic reaction using glucose oxidase, peroxidase and a chromogen. Glucose oxidase catalyzes the formation of gluconic acid and hydrogen peroxide via the oxidation of glucose. Peroxidase then catalyzes the reaction of hydrogen peroxide with a chromogen via the oxidation of chromogen to colors ranging between green to gray-blue.

Occult Blood-pseudo-enzymatic test containing organic peroxide and a chromogen. The peroxidase effect of hemoglobin and myoglobin causes a color change to green.

Urobilinogen- based on the coupling reaction of urobilinogen with a stable diazonium salt in buffer. A pink to red color proportional to the urobilinogen concentration is generated.

pH- this test contains a mixed indicator which assures a marked change in color between pH 5 and pH 9.

Nitrite-This test is based on modified Griess reaction in which Nitrite in the urine reacts with amide to form a diazonium compound. The subsequent coupling reaction yields a pink color in the presence of nitrite.

Specific Gravity- Specific gravity is physically determined by refractometry in the urine chemistry system and is not analyzed by strip chemistry.

Leukocyte Peroxidase - enzymatic test pad containing an indoxyl ester and a diazonium salt. Granulocyte esterases react with indoxyl ester and diazonium salt to generate a violet color.

Ascorbic Acid-This test is based on Tilman's reaction in which the presence of ascorbic acid leads to the decolorization of the test pad from gray-blue to orange.

Ketones-based on Legal's method in which the test pad contains sodium nitroprusside and glycine in an alkaline medium. A violet color proportional to methylketone is generated.

Protein- based on the "protein error" of pH indicators on the green color developed from the presence of protein.

Bilirubin- based on the coupling of bilirubin with diazonium salt in an acidic medium. A pinkish tan color proportional to bilirubin concentration is generated.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

   a. Precision/Reproducibility:

Repeatability (within run and day-to-day) precision of the iChem VELOCITY automated urine chemistry system was evaluated using a negative urine pool which was spiked at the lowest positive level and the highest positive level. Three replicate tubes of each level (negative, low positive, and high positive) were analyzed on three iChem Velocity analyzers with three lots of iChem VELOCITY Urine Chemistry Strips for 20 non-consecutive runs/days. The within-run precision is calculated as an average direct agreement for the 20 runs over the 3 replicate for all instruments and strip lots. The day-to-day precision is calculated as an average direct agreement of all 20 1st replicates of each run for all instruments and strip lots. All concentrations for all tests had 100% agreement at +/- one color block.

Example: 3 replicates (1 negative sample + 2 positive samples) x 3 instruments x 3 strip lots x 20 runs = 540 replicates

Precision: Day-to-Day

Level I:

Analyte	Level	Unit	Direct Agreement (%)	± 1 block Agreement (%)	N
BILIRUBIN	0	mg/dL	100	100	180
UROBILINOGEN	0	mg/dL	100	100	180
KETONES	0	mg/dL	99.8	100	180
ASCORBIC ACID	0	mg/dL	100	100	180
GLUCOSE	0	mg/dL	100	100	180
PROTEIN	0	mg/dL	100	100	180
BLOOD	0	mg/dL	100	100	180
pH	5	-	100	100	180
NITRITE	0	mg/dL	100	100	180
LEUKOCYTES	0	WBC/µL	100	100	180

Level II:

Analyte	Level	Unit	Direct Agreement (%)	± 1 block Agreement (%)	N
BILIRUBIN	2	mg/dL	95.2	100	180
UROBILINOGEN	2	mg/dL	96.1	100	180
KETONES	5	mg/dL	100	100	180
ASCORBIC ACID	20	mg/dL	96.1	100	180
GLUCOSE	50	mg/dL	97.2	100	180
PROTEIN	30	mg/dL	98.9	100	180
BLOOD	0.03	mg/dL	97.2	100	180
pH	7	-	100	100	180
NITRITE	Pos.	mg/dL	99.4	100	180
LEUKOCYTES	25	WBC/µL	96.1	100	180

Level III:

Analyte	Level	Unit	Direct Agreement (%)	± 1 block Agreement (%)	N
BILIRUBIN	4	mg/dL	100	100	180
UROBILINOGEN	4	mg/dL	100	100	180
KETONES	80	mg/dL	100	100	180
ASCORBIC ACID	40	mg/dL	99.4	100	180
GLUCOSE	500	mg/dL	100	100	180
PROTEIN	500	mg/dL	100	100	180
BLOOD	1.0	mg/dL	98.9	100	180
pH	9	-	97.8	100	180
NITRITE					
LEUKOCYTES	500	WBC/µL	100	100	180

Precision: Within Run

Level I:

Analyte	Level	Unit	Direct Agreement (%)	± 1 block Agreement (%)	N
BILIRUBIN	0	mg/dL	100	100	540
UROBILINOGEN	0	mg/dL	100	100	540
KETONES	0	mg/dL	100	100	540
ASCORBIC ACID	0	mg/dL	100	100	540
GLUCOSE	0	mg/dL	100	100	540
PROTEIN	0	mg/dL	100	100	540
BLOOD	0	mg/dL	100	100	540
pH	5	-	100	100	540
NITRITE	0	mg/dL	100	100	540
LEUKOCYTES	0	WBC/µL	100	100	540

Level II:

Analyte	Level	Unit	Direct Agreement (%)	± 1 block Agreement (%)	N
BILIRUBIN	2	mg/dL	96.1	100	540
UROBILINOGEN	2	mg/dL	96.3	100	540
KETONES	5	mg/dL	99.4	100	540
ASCORBIC ACID	20	mg/dL	97.6	100	540
GLUCOSE	50	mg/dL	95.6	100	540
PROTEIN	30	mg/dL	98.9	100	540
BLOOD	0.03	mg/dL	97.8	100	540
pH	7	-	100	100	540
NITRITE	Pos.	mg/dL	99.4	100	540
LEUKOCYTES	25	WBC/µL	96.3	100	540

Level III:

Analyte	Level	Unit	Direct Agreement (%)	± 1 block Agreement (%)	N
BILIRUBIN	4	mg/dL	100	100	540
UROBILINOGEN	4	mg/dL	100	100	540
KETONES	80	mg/dL	99.4	100	540
ASCORBIC ACID	40	mg/dL	99.8	100	540
GLUCOSE	500	mg/dL	100	100	540
PROTEIN	500	mg/dL	100	100	540
BLOOD	1.0	mg/dL	98	100	540
pH	9	-	97.6	100	540
NITRITE					
LEUKOCYTES	500	WBC/µL	100	100	540

b. Linearity/assay reportable range:

Please see the method comparison section 2.a below and detection limit 2.d. below.

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

IRISpec CA/CB/CC controls previously cleared under (k072640) are to be used with the iChem® VELOCITY™ automated urine chemistry system and iChem® VELOCITY™ test strips.

Traceability

The IChem Velocity CalChek reagents are traceable to the following:

Consumable	Reference Instrument	Traceability
SG Calchek	Atago Model SUR-NE refractometer	The Atago Model SUR-NE refractometer is calibrated annually to an outside calibration laboratory certified to ISO/IEC 17025
Color CalCheks	Shimatzu model 1601 spectrophotometer	The Shimatzu spectrophotometer is calibrated annually to an outside calibration laboratory certified to ISO/TEC 17025
Clarity CalCheks	Hanna HI 93414 Turbidity Meter	AMCO® Turbidity 1000 and AMCO® Turbidity 4000 Turbidity Standards, which are components of the Clarity Cal Cheks, are NIST traceable standards.

Stability

Real Time, open vial and accelerated stability protocols were reviewed and found to be acceptable. The iChem® VELOCITY ™ CalChek Reagents are for single use only and have an open vial stability for up to 8 hours, with a single repeat, and a shelf-life of 1 year when stored at 18˚C to 25˚C (65˚F-77˚F).

Value Assignment

SG Color Cal Cheks- NaCl and/or Glycerol are added gravimetrically to deionized water to obtain values that span the range of the assay on the instrument. Comparison testing was performed on three lots of proposed CalChek control material and compared with human urine spiked with NaCl. Testing was performed in triplicate on the iChem ®VELOCITY™. No significant measurement differences were found.

SG Color Cal Cheks- varying amounts of food color are blending to achieve desired shades of colorless, straw, normal yellow and amber. The correct color absorbance values are verified by a spectrophotometer at 450, 550, and 650 nm.

Clarity CalCheks-varying amounts of food coloring and AMCO® turbidity standards are added to deionized water to achieve the desired clarity of slightly cloudy, cloudy and turbid. The achieved clarity is verified by nephlometric turbidity units obtained from a turbidity meter.

An example of the CalChek reagent values are as follows:

CalChek#	**CalChek Name**
1	SG 1.002
2	SG 1.030
3	SG 1.060
4	Colorless
5	Straw
6	Yellow
7	Amber
8	Slightly-Cloudy
9	Cloudy
10	Turbid

d. Detection limit:

The sensitivity of the iChem® VELOCITY™ Urine Chemistry Strips was evaluated by spiking negative urine pools with known quantities of analytes. The analytes were spiked at the middle of each positive color block as well as between the negative and the first positive color block. Multiple samples were tested for each concentration. The prepared samples were then assayed on three iChem®VELOCITY™ analyzers. Sensitivity was defined as the lowest concentration that will yield ≥ 67% positive results.

Analyte (Unit of Measure)	Sensitivity
Bilirubin (mg/dL)	1.8
Urobilinogen (mg/dL)	1.6
Ketones (mg/dL)	3.0
Ascorbic Acid (mg/dL)	17
Glucose (mg/dL)	20
Protein (mg/dL)	20
Blood (Hemoglobin) (mg/dL	0.02
Nitrite (mg/dL)	0.04
Leukocytes (WBC/µL)	15

e. *Analytical specificity:*
Negative urine was spiked one at a time with the possible interfering substances with concentrations listed in the following table. Each urine sample was tested with 5 replicates using an iChem® VELOCITY™ instrument and strips. Possible interference was determined when a difference of one color pad in any of the five replicates for the particular test analyte compared to either the negative (specificity) or analyte-spiked positive sample (interference).
The following potentially interfering substances at concentrations indicated were added to the urine. The noted interferences are stated in the labeling.

Interfering Substance	Interfering Substance Conc. (mg/dL)	Negative Urine With Spiked Substances
Acetoacetate	250	Positive with Ketone. Negative for others
Ammonium Chloride	200	All Negative
Albumin	1000	Positive with Protein. Negative for others. Increased SG
Ascorbic Acid	>300	Positive for Ascorbic. False negative bilirubin, ↓glucose, hemoglobin and nitrite
Bilirubin	4	Positive for Bilirubin and Urobilinogen.

		Negative for others
Calcium Chloride	80	All negative
Citric Acid	65	All negative. Lowered pH
Creatinine	600	All negative. Increased SG.
D (+) Glucose	4100	Positive for Glucose. Negative for others. Increased SG
Glycine	450	All negative. Increased SG
Hemoglobin	5	Positive for blood. Negative for others.
Potassium chloride	1200	All negative. Increase SG
Sodium Chloride	1800	All negative. Increased SG
Oxalic Acid	70	All Negative. Lowered pH
Sodium Nitrate	0.3	All negative
Sodium Nitrite	10	Positive for nitrite. Negative for others.
Sodium Phosphate	500	All negative. Increased SG
Urea	4000	All negative. Increased SG
D(+) Galactose	0.5	All negative
Beta-Lactose	1	All negative
2-mercaptoethanesulphonate (MESNA)	Up to 1140	False positive for glucose, ketone, and ascorbic acid. All others negative.
Cephalosporin	60	May ↓ leukocyte esterase reading All others negative
Boric Acid	1000	May ↓ leukocytes esterase reading. All others negative.
Tetracycline	1.5	All negative

f. Assay cut-off:

Not applicable

2. Comparison studies:

a. Method comparison with predicate device:

A method comparison study was performed using a single replicate of each clinical specimen between a single lot or reagent test strips and the iChem 100 analyzer with a single lot of iChem 10SG reagent strips. A minimum of 50 clinical samples were analyzed for the first positive color block above the negative. No spiked samples were used. For the second and successive color blocks above the lowest color block a minimum of 40 clinical samples were analyzed. Clinically positive spiked samples were used when insufficient numbers of high concentration samples were not available.

Ascorbic Acid

iChemVELOCITY (mg/dL)	40			**40**
	20	1	**47**	
	0	**326**	2	
		0	20	40
iChem 100 (mg/dL)				
Exact Agreement		99.7%	95.9%	100%
Agreement +/- 1 Grade		100%	100%	100%

Bilirubin

iChemVELOCITY (mg/dL)	4			**40**
	2	2	**36**	
	0	**338**		
		0	2	4
iChem 100 (mg/dL)				
Exact Agreement		99.4%	100%	100%
Agreement +/- 1 Grade		100%	100%	100%

Blood

iChemVELOCITY (mg/dL)	1.0				**38**
	0.2		4	**34**	2
	0.03		**50**	2	
	0	**300**			
		0	0.030	0.2	1.0
iChem 100 (mg/dL)					
Exact Agreement		100%	92.6%	94.4%	95%
Agreement +/- 1 Grade		100%	100%	100%	100%

Glucose

iChemVELOCITY (mg/dL)	500				**37**
	150			**34**	4
	50		**48**	22	
	0	**300**			
		0	50	150	500 - 1000
iChem 100 (mg/dL					
Exact Agreement		100%	100%	60.7%*	90.2%
Agreement +/- 1 Grade		100%	100%	100%	100%

*The sponsor states in the labeling, this discrepancy is due to the reflectance border separating 50 from 150 mg/dL. This design concept results in reduced concordance at the 50/150 border.

Ketones

iChemVELOCITY (mg/dL)					
	80				11
	20		2	20	
	5	1	28		
	0	19			
		0	25	100	300
iChem 100 (mg/dL)					
Exact Agreement		95%	93.3%	100%	100%
Agreement +/- 1 Grade		100%	100%	100%	100%

Leukocytes

iChemVELOCITY (mg/dL)						
	500					40
	75		5	11		
	25	4	62	4		
	0	323	5			
		0	25	75		500
iChem 100 (mg/dL)						
Exact Agreement		98.8%	86.1%	73.3%		100%
Agreement+=/- 1 Grade		100%	100%	100%		100%

Nitrite

iChemVELOCITY (mg/dL)			
	Pos		48
	0	324	2
		0	0.1
iChem 100 (mg/dL)			
Exact Agreement		100%	96.0%
Agreement +/- 1 Grade		100%	100%

pH

iChemVELOCITY (mg/dL)	9					**10**
	8				**8**	
	7			**10**	2	
	6	3	**7**			
	5	**10**				
		5	6	7	8	9
iChem 100 (mg/dL)						
Exact Agreement		76.9%	100%	100%	80%	100%
Agreement +/- 1 Grade		100%	100%	100%	100%	100%

Protein

iChemVELOCITY (mg/dL)	500				**35**
	100		5	**38**	2
	30		**46**		
	0	**324**			
		0	30	100	500
iChem 100 (mg/dL)					
Exact Agreement		100%	90.2%	100%	94.6%
Agreement +/- 1 Grade		100%	100%	100%	100%

Urobilinogen

iChemVELOCITY (mg/dL)	4		3	**35**
	2		**47**	2
	0	**366**		
		0	2	4
iChem 100 (mg/dL)				
Exact Agreement		100%	94%	95%
Agreement +/- 1 Grade		100%	100%	100%

Specific Gravity was analyzed by comparing iChem®VELOCITY™ to the ATAGO PEN Refractometer. Values ranged from 1.000 to 1.060 in increments of 0.005 SG units. A total of 240 specimens natural urine samples were analyzed.

S.G. semi-quatitative Concordance iChemVELOCITY vs Atago PEN Refractometer

iChemVELOCITY	1.005	1.010	1.015	1.020	1.025	1.030	1.035	1.040	1.045	1.050	1.055	1.060
1.060												20
1.055											20	
1.050										20		
1.045									20			
1.040								20				
1.035							20					
1.030						19						
1.025					20	1						
1.020				19								
1.015			20	1								
1.010		20										
1.005	20											
	1.005	1.010	1.015	1.020	1.025	1.030	1.035	1.040	1.045	1.050	1.055	1.060

Atago PEN Refractometer

Total	20	20	20	20	20	20	20	20	20	20	20	20
Agreement:												
Exact	100%	100%	100%	95%	100%	95%	100%	100%	100%	100%	100%	100%
± 1 Grade	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%

b. Matrix comparison:

Not applicable. The device is for urine samples only.

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:

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

N. Instrument Name:

iChem®VELOCITY ™ Automated Urine Chemistry System

O. System Descriptions:

1. Modes of Operation:

   Single and continuous testing mode

2. Software:

   FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:

   Yes ___X_____ or No _____

3. Specimen Identification:

   Bar Code Reader and Manual numeric entry

4. Specimen Sampling and Handling:

   The iChem®VELOCITY™ Urinalysis Test system can analyze multiple samples. Test strips are dispensed from the strip provider module, and places face up on the strip conveyer system. The sample probe mixes the specimen, then aspirates an aliquot of urine from the sample tube and dispenses the sample onto each reagent pad.

5. Calibration:

   The instrument uses the accompanying five Cal Chek strips to perform a calibration reflectance check. The five Cal Chek strips have fixed calibration values with no lot specific values. Cal Chek strips are single use only. The sponsor recommends that the device be calibrated on a quarterly basis.

6. Quality Control:

   Recommendations for testing quality control are provided in the labeling. The condition and accuracy of the system can be check by performing control measurements using urine control CA/CB/CC. The iChem® VELOCITY™ supports the use of three control solutions (CA, CB, and CC) to validate the positive responses for each urine chemistry.

P. Other Supportive Instrument Performance Characteristics Data Not Covered In The "Performance Characteristics" Section above:

None.

Q. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

R. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.