October 30, 2018

Ortho-Clinical Diagnostics, Inc.
Marlene Hanna
Director, Regulatory Affairs
100 Indigo Creek Drive
Rochester, NY 14626

Re: K182072
Trade/Device Name: VITROS Chemistry Products Cl-Slides
VITROS Chemistry Products ECO2 Slides
VITROS Chemistry Products GLU Slides
Regulation Number: 21 CFR 862.1170
Regulation Name: Chloride test system
Regulatory Class: Class II
Product Code: CGZ, KHS, CGA
Dated: July 30, 2018
Received: August 1, 2018

Dear Marlene Hanna:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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 Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Kellie B. Kelm -S

for 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
k182072

Device Name
VITROS Chemistry Products Cl- Slides
VITROS Chemistry Products ECO2 Slides
VITROS Chemistry Products GLU Slides

Indications for Use *(Describe)*

1. VITROS Chemistry Products Cl- Slides: Rx Only. For in vitro diagnostic use only. VITROS Chemistry Products Cl- Slides quantitatively measure chloride (Cl-) concentration in serum, plasma and urine using VITROS 250/350/5,1 FS and 4600 Chemistry Systems and the VITROS 5600/ XT 7600 Integrated Systems. Chloride measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders such as cystic fibrosis and diabetic acidosis.

2. VITROS Chemistry Products ECO2 Slides: Rx Only. For in vitro diagnostic use only. VITROS Chemistry Products ECO2 Slides quantitatively measure total carbon dioxide (CO2) concentration in serum and plasma using VITROS 250/350/950/5,1 FS and 4600 Chemistry Systems and the VITROS 5600/ XT 7600 Integrated Systems. Bicarbonate/ carbon dioxide measurements are used in the diagnosis and treatment of numerous potentially serious disorders associated with changes in body acid-base balance.

3. VITROS Chemistry Products GLU Slides: Rx Only. For in vitro diagnostic use only.
VITROS Chemistry Products GLU Slides quantitatively measure glucose (GLU) concentration in serum, plasma, urine, and cerebrospinal fluid using VITROS 250/350/950/5,1 FS and 4600 Chemistry Systems and the VITROS 5600/ XT 7600 Integrated Systems. Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, and idiopathic hypoglycemia, and of pancreatic islet cell carcinoma.

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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5 510(k) Summary Information

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and
21 CFR 807.92.

The assigned 510(k) number is: k182072

Submitter's Information
Ortho-Clinical Diagnostics, Inc.
100 Indigo Creek Drive
Rochester, New York 14626-5101
Phone: (585) 453-4041
Fax: (585) 453-3368

Contact Person:
Marlene Hanna, RAC
Director, Regulatory Affairs

Date of Preparation: July 30, 2018

Device Proprietary Name(s):

VITROS Chemistry Products Cl- Slides
VITROS Chemistry Products ECO2 Slides
VITROS Chemistry Products GLU Slides

Common Names:

Chloride assay
Carbon dioxide assay
Glucose assay

Classification Names

VITROS	Product Code	Class	Regulation Section	Panel
Cl-	CGZ	Class II	21 CFR 862. 1170 chloride test system	Clinical Chemistry
ECO2	KHS	Class II	21 CFR 862. 1160 carbon dioxide test system	
GLU	CGA	Class II	21 CFR 862. 1345 glucose test system	

Predicate Device(s)

No.	New Devices	Predicate Devices	Predicate Device FDA 510(k) Number
1	VITROS Chemistry Products Cl- Slides	VITROS Chemistry Products Cl- Slides	k162020
2	VITROS Chemistry Products ECO2 Slides	VITROS Chemistry Products ECO2 Slides	k120765
3	VITROS Chemistry Products GLU Slides	VITROS Chemistry Products GLU Slides	k163433

Intended Use Statement(s)

1. VITROS Chemistry Products Cl- Slides
Rx Only. For in vitro diagnostic use only. VITROS Chemistry Products Cl- Slides quantitatively measure chloride (Cl-) concentration in serum, plasma and urine using VITROS 250/350/5,1 FS and 4600 Chemistry Systems and the VITROS 5600/ XT 7600 Integrated Systems. Chloride measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders such as cystic fibrosis and diabetic acidosis.

2. VITROS Chemistry Products ECO2 Slides
Rx Only. For in vitro diagnostic use only. VITROS Chemistry Products ECO2 Slides quantitatively measure total carbon dioxide (CO2) concentration in serum and plasma using VITROS 250/350/950/5,1 FS and 4600 Chemistry Systems and the VITROS 5600/ XT 7600 Integrated Systems. Bicarbonate/carbon dioxide measurements are used in the diagnosis and treatment of numerous potentially serious disorders associated with changes in body acid-base balance.

3. VITROS Chemistry Products GLU Slides
Rx Only. For in vitro diagnostic use only.
VITROS Chemistry Products GLU Slides quantitatively measure glucose (GLU) concentration in serum, plasma, urine, and cerebrospinal fluid using VITROS 250/350/950/5,1 FS and 4600 Chemistry Systems and the VITROS 5600/ XT 7600 Integrated Systems. Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, and idiopathic hypoglycemia, and of pancreatic islet cell carcinoma.

Device Description

The VITROS Chemistry MicroSlide range of products (in this case VITROS Chemistry Products Cl- Slides, VITROS Chemistry Products ECO2 Slides, and VITROS Chemistry Products GLU

Slides), are combined with the VITROS XT 7600 Integrated System to perform the VITROS Cl-, ECO2, and GLU assays.

Comparison to Predicate Devices

The following tables show similarities and differences between the new and predicate devices.

Table 1 VITROS Chemistry Products Cl- Slides

Similarities		
Device Characteristic	**Candidate VITROS Cl- Slides**	**Predicate Device VITROS Cl- Slides k162020**
Intended Use	Rx Only. For in vitro diagnostic use only. VITROS Chemistry Products Cl- Slides quantitatively measure chloride (Cl-) concentration in serum, plasma and urine.	Same
Method Principle	Potentiometric; Electrode (ISE), Direct (undiluted)	Same
Reactive Ingredients per cm^2	Silver 0.4 mg and silver chloride 0.2 mg	Same
Sample type	Serum and plasma, urine	Same
Sample volume	10 µL	Same
Measuring Range	Serum: 50.0 -175.0 mmo/L Urine: 15-300 mmol/L	Same
Differences		
Device Characteristic	**Candidate VITROS Cl- Slides**	**Predicate Device VITROS Cl- Slides k162020**
Instrumentation	VITROS 250/350/950/5,1 FS and 4600 Chemistry Systems and the VITROS 5600/ **XT 7600** Integrated System	VITROS 250/350/950/5,1 FS and 4600 Chemistry Systems and the VITROS 5600 Integrated System

Table 2 VITROS Chemistry Products ECO2 Slides

Similarities		
Device Characteristic	**Candidate VITROS ECO2 Slides**	**Predicate Device VITROS ECO2 Slides K120765**
Intended Use	Rx Only. For in vitro diagnostic use only. VITROS Chemistry Products ECO2 Slides quantitatively measure total carbon dioxide (CO2) concentration in serum and plasma.	Same
Basic principle	Enzymatic Endpoint	Same
Reactive Ingredients per cm^2	Phosphoenolpyruvate carboxylase (bacteria) 0.20 U; malate dehydrogenase (porcine heart) 0.26 U; phosphoenolpyruvate 0.39 mg and nicotinamide adenine dinucleotide, reduced 0.44 mg	Same
Wavelength	340 nm	Same
Sample type	Serum, plasma	Same
Sample volume	6 μL	Same
Measuring Range	5-40 mmol/L	
Differences		
Device Characteristic	**Candidate VITROS ECO2 Slides**	**Predicate Device VITROS ECO2 Slides k120765**
Instrumentation	VITROS 250/350/950/5,1 FS and 4600 Chemistry Systems and the VITROS 5600/ **XT 7600** Integrated System	VITROS 250/350/950/5,1 FS and 4600 Chemistry Systems and the VITROS 5600 Integrated System

Table 3 VITROS Chemistry Products GLU Slides

Similarities		
Device Characteristic	**Candidate VITROS GLU Slides**	**Predicate Device VITROS GLU Slides** (k163433)
Intended Use	Rx Only. For in vitro diagnostic use only. VITROS Chemistry Products GLU Slides quantitatively measure glucose (GLU) concentration in serum, plasma, urine, and cerebrospinal fluid	Same
Basic principle	Colorimetric	Same
Reactive Ingredients per cm^2	Glucose oxidase (*Aspergillus sp.*) 0.77 U; peroxidase (horseradish root) 3.6 U; 1,7-dihydroxynaphthalene (dye precursor) 67 µg and 4-aminoantipyrine hydrochloride (dye precursor) 0.11 mg.	Same
Wavelength	540 nm	Same
Sample type	Serum, plasma, urine, CSF	Same
Sample volume	6 µL	Same
Measuring Range	Serum: 20.0-625.0 mg/dL Urine and CSF: 20.0-650.0 mg/dL	Same
Differences		
Device Characteristic	**Candidate VITROS GLU Slides**	**Predicate Device VITROS GLU Slides** (k163433)
Instrumentation	VITROS 250/350/950/5,1 FS and 4600 Chemistry Systems and the VITROS 5600/ **XT 7600** Integrated System	VITROS 250/350/950/5,1 FS and 4600 Chemistry Systems and the VITROS 5600 Integrated System

Method Comparison

Method comparison studies were conducted by testing a minimum of 125 human serum samples with analyte concentrations within the measuring ranges (MR) of chloride, carbon dioxide and glucose assays on the VITROS XT 7600 Integrated System and the VITROS 5600 Integrated System (predicate device).

In addition, 125human urine samples were tested for chloride and 125 human urine samples and 125 human CSF samples were tested for glucose on the candidate and predicate test systems. The results are summarized below:

Summary of VITROS XT 7600 Method Comparison Regression Analysis Data

VITROS assay	# Samples Tested	# Samples < MR, >MR	N	Regression Analysis	Slope	Intercept	Test range	Claimed Measuring Range
CL-Serum (mmol/L)	125	0	125	Passing Bablok	1.00	-0.11	51.2-167.5	50.0-175.0
Cl-Urine (mmol/L)	125	2	123	Weighted Deming	1.00	-0.11	15-290	15-300
ECO2 Serum (mg/dL)	125	1	124	Deming	0.99	0.19	7.1-38.4	5.0-40.0
GLU serum (mg/dL)	125	1	124	Weighted Deming	1.00	0.49	22.1-593.8	20.0-625.0
GLU Urine (mg/dL)	125	0	125	Weighted Deming	1.00	0.28	25.3-600.4	20.0-650.0
GLU csf (mg/dL)	125	0	125	Weighted Deming	1.00	0.22	22.9-649.5	20.0-650.0

MR=measuring range

In addition to the above mentioned method comparison studies, testing was performed to determine the precision, linearity, limit of detection, and Interfering substances of the representative VITROS assays on the VITROS XT 7600 System.

Precision

Precision studies were conducted following EP05-A3, *Evaluation of Precision of Quantitative Measurement Procedures, Approved Guidelines* – Third Edition (2014). The study was performed by testing a minimum of two Quality control fluids and three human based precision fluids using the chloride (Cl-), carbon dioxide (ECO2), and glucose (GLU) assays.

Samples were analyzed using one VITROS XT 7600 Integrated System over 20 days, with 2 runs per day and 2 replicates per specimen (n=80).

Cl- Serum (mmol/L) Precision Table

				Repeatability (Within Run)		Within Day		Between Day		Between Cal		Within Lab (Total)	
System	**Fluid ID**	**Mean**	**N**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**
7600	CLS-5903-1	86	80	0.4	0.5	0.5	0.6	0.6	0.7	0.6	0.7	1.0	1.2
7600	CLS-5905-2	108	80	0.4	0.4	0.6	0.5	0.7	0.7	0.7	0.6	1.2	1.1
7600	CLS-PP1	66	80	0.3	0.4	0.4	0.5	0.2	0.3	0.5	0.7	0.6	0.9
7600	CLS-PP4	127	80	0.4	0.4	0.6	0.4	0.4	0.3	1.2	0.9	1.4	1.1
7600	CLS-PP5	160	80	0.6	0.4	0.6	0.4	0.4	0.2	1.6	1.0	1.8	1.1
7600	CLS-SRM	106	80	0.4	0.3	0.5	0.5	0.3	0.3	1.0	0.9	1.2	1.1

Cl- Urine (mmol/L) Precision Table

				Repeatability (Within Run)		Within Day		Between Day		Between Cal		Within Lab (Total)	
System	**Fluid ID**	**Mean**	**N**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**
7600	CLU-66791-1	101	80	0.4	0.3	0.6	0.6	0.2	0.2	0.7	0.7	0.9	0.9
7600	CLU-66792-2	189	80	0.5	0.3	0.9	0.5	0.4	0.2	2.1	1.1	2.3	1.2
7600	CLU-PP1	22	80	0.3	1.3	0.5	2.2	0.2	1.0	0.2	0.9	0.6	2.6
7600	CLU-PP3	151	80	0.4	0.3	0.5	0.4	0.5	0.3	0.6	0.4	0.9	0.6
7600	CLU-PP5	249	80	0.7	0.3	1.0	0.4	1.2	0.5	3.6	1.4	3.9	1.6
7600	CLU-URN	67	80	0.3	0.4	0.3	0.5	0.2	0.4	0.5	0.7	0.6	0.9

ECO2 (mmol/L) Precision Table

				Repeatability (Within Run)		Within Day		Between Day		Between Cal		Within Lab (Total)	
System	**Fluid ID**	**Mean**	**N**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**
7600	ECO2-5903-1	26	80	0.3	1.0	0.4	1.4	0.5	1.9	0.0	0.0	0.6	2.4
7600	ECO2-5905-2	16	80	0.3	21.7	0.4	2.5	0.1	0.6	0.3	1.8	0.5	3.1
7600	ECO2-PP1	8	80	0.3	3.2	0.4	4.5	0.1	1.5	0.4	5.6	0.6	7.4
7600	ECO2-PP3	17	80	0.3	1.5	0.3	2.0	0.1	0.6	0.2	1.4	0.4	2.5
7600	ECO2-PP5	33	80	0.3	0.8	0.4	1.3	0.4	1.2	0.3	0.8	0.6	1.9
7600	ECO2-SRM	26	80	0.2	0.8	1.1	4.2	0.4	1.5	0.0	0.0	1.2	4.4

GLU (mg/dL) Serum Precision Table

				Repeatability (Within Run)		Within Day		Between Day		Between Cal		Within Lab (Total)	
System	Fluid ID	Mean	N	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
7600	GLUS32-5903-1	89	80	0.4	0.4	0.6	0.7	0.5	0.6	0.0	0.0	0.8	0.9
7600	GLUS32-5905-2	282	80	1.1	0.4	1.4	0.5	1.9	0.7	1.0	0.4	2.6	0.9
7600	GLUS32-PP1	27	80	0.2	0.7	0.3	1.2	0.3	1.1	0.2	0.9	0.5	1.8
7600	GLUS32-PP3	116	80	0.5	0.4	0.6	0.5	0.5	0.4	0.2	0.2	0.8	0.7
7600	GLUS32-PP5	566	80	1.7	0.3	2.5	0.4	2.4	0.4	5.0	0.9	6.1	1.1
7600	GLUS32-SRM	99	80	0.3	0.3	0.5	0.5	0.5	0.5	0.3	0.3	0.8	0.8

GLU (mg/dL) Urine Precision Table

				Repeatability (Within Run)		Within Day		Between Day		Between Cal		Within Lab (Total)	
System	Fluid ID	Mean	N	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
7600	GLU32-66791-1	29	80	0.2	0.6	0.4	1.3	0.3	1.2	0.4	1.4	0.7	2.2
7600	GLU32-66792-2	285	80	1.4	0.5	2.3	0.8	0.9	0.3	0.8	0.3	2.6	0.9
7600	GLU32-PP2	102	80	0.4	0.4	0.7	0.7	0.6	0.6	1.2	1.2	1.5	1.5
7600	GLU32-PP3	232	80	1.1	0.5	2.4	1.0	3.5	1.5	0.9	0.4	4.3	1.9
7600	GLU32-PP5	593	80	1.9	0.3	2.7	0.5	6.5	1.1	7.2	1.2	10.0	1.7

GLU (mg/dL) CSF Precision Table

				Repeatability (Within Run)		Within Day		Between Day		Between Cal		Within Lab (Total)	
System	Fluid ID	Mean	N	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
7600	GLUC32-5706-1	36	80	0.2	0.6	0.3	0.9	0.4	1.0	0.2	0.5	0.5	1.4
7600	GLUC32-5707-2	84	80	0.4	0.5	0.5	0.6	0.3	0.4	0.2	0.2	0.6	0.8
7600	GLUC32-CSF	41	80	0.2	0.5	0.3	0.6	0.3	0.9	0.2	0.4	0.5	1.2
7600	GLUC32-PP1	28	80	0.1	0.5	0.3	1.1	0.3	1.2	0.3	0.9	0.5	1.9
7600	GLUC32-PP4	289	80	1.3	0.5	1.7	0.6	1.4	0.5	2.2	0.7	3.1	1.1
7600	GLUC32-PP5	563	80	2.6	0.5	3.7	0.7	3.6	0.6	2.8	0.5	5.8	1.0

Linearity

Linearity studies were performed according to CLSI EP06-A, *Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach Approved Guideline (2003).* VITROS Cl- Slides, VITROS ECO2 Slides, and VITROS GLU Slides were tested on the VITROS XT 7600 Integrated System. A series of eleven proportionally related admixtures of low and high test fluids were tested to verify linearity; each sample was tested in triplicate, a minimum of two replicates was acceptable for analysis.

The linearity studies support the claimed measuring ranges for the VITROS Cl-, VITROS ECO2, and VITROS GLU assays.

Detection Limits

Detection capability studies for each analyte were evaluated based upon CLSI EP17-A2, *Evaluation of Detection Capability for Clinical Laboratory Measurements Procedures: Approved Guidelines – Second Edition (2012*).

Limit of blank (LoB) studies were performed by testing 4 blank samples. Samples were tested in replicates of 6 over 3 days, using 3 lots of reagents, 4 samples every day, for a total of 216 observations (72 results per reagent lot). The LoB value for each assay was defined as the highest value achieved using blank samples with the stated probability (i.e. $\alpha = 5\%$). Since the data for all assays were non-gaussian, a non-parametric approach was applied that estimates the LoB using the calculated rank position corresponding to the 95th percentile of the distribution of blank values observed."

Limit of detection (LoD) studies were performed by testing 4 pools of human samples with analyte concentrations close to the expected detection limit for each analyte. Samples were tested in replicates of 6 over 3 days, using 3 lots of reagents, with the 4 human sample pools every day, for a total of 216 observations (72 results per reagent lot). The data were analyzed according to CLSI EP17-A2, using CLSI-approved statistical software Analyse-it version 4.95.4, Method Validation Edition (Analyse-it Software Limited, Leeds UK). The software calculated LoD using a pooled SD from the low level fluid results and the input LoB value for the assay, determined as described above. The LoD value for the assay is the highest resultant value achieved among the combinations of reagent lots and human pools evaluated, with the stated probability (i.e. $\beta = 5\%$).

Limit of Quantitation studies were performed using 4 pools of low level samples with analyte concentrations close to the expected LoQ of the corresponding assay. Samples were tested in replicates of 4 over 3 days, using 3 lots of reagents, 4 samples every day, for a total of 144 observations (48 results per reagent lot). Ortho defines LoQ as the lowest concentration with an imprecision of $\leq$20% and percent total allowable error $\leq$ 8% for chloride (serum); imprecision of $\leq$5 % and percent total allowable error $\leq$ 10% for chloride (urine), imprecision of $\leq$20% and percent total allowable error $\leq$ 30% for carbon dioxide, and imprecision of $\leq$20% and total allowable error $\leq$ 30% for glucose in serum, urine, and CSF.

The results of the detection capability studies for each assay are presented in the table below.

	Cl- Serum (mmol/L)	Cl- Urine (mmol/L)	ECO2 (mmolL)	GLU (mg/dL)		
				Serum	Urine	CSF
LoB	9.2202	3.0965	1.9944	4.5753	6.2966	4.0745
LoD	9.9798	4.0417	2.3522	5.2670	6.7212	4.6992
LoQ	49	11	3.7	13	20	19
Claimed LoQ	50	15	5.0	20	20	20
Assay Range	50.0-175.0	15-300	5.0-40.0	20.0-625.0	20.0-650.0	20.0-650.0

Specificity

Interference Testing was performed in accordance with CLSI EP07-A2, *Interference Testing in Clinical Chemistry, Approved Guidance—Second Edition. Clinical and Laboratory Standards Institute. November 2005*, using VITROS Cl^-, VITROS ECO2 and VITROS GLU assays.

Assays were tested on one VITROS XT 7600 Integrated System ('VITROS XT 7600, Test System) and one VITROS 5600 Integrated System (VITROS 5600, Predicate/Control System). Testing on the representative assays included known chemical interferents, common chemical substances identified with potential to interfere based upon risk assessment, as well as several claimed non-interferents. If hemoglobin, bilirubin, and/or intralipid were not previously identified as known interferents for the representative assays, Hemolysis, Icterus and/or Turbidity (HIT) indices, respectively, were evaluated during testing. Testing employed "paired-difference" assessment at a minimum of two analyte levels, as specified by CLSI EP07-A2.

*****VITROS Chemistry Products MicroSensor™: Sub-system of analyzer that performs automated semi-quantitative sample quality index determinations on serum/plasma and cerebrospinal fluid samples. The sample quality index determinations performed are hemolysis, icterus, and turbidity; also referred to as 'HIT indices' or 'sample integrity indices'.

Results were evaluated as follows:

Known Interferents: The observed bias was compared to predetermined acceptance criteria (the Maximum Allowable Interference (MAI)) per product design input, and the Claimed Bias derived from product claims.

- If the observed bias was within the MAI criteria (either in a positive or negative direction) and/or less than the Claimed Bias, performance was acceptable.
- If the observed bias was greater than the Claimed Bias, the bias was compared to the 95% Confidence Limit (one-sided) per CLSI EP07-A2. If the Claimed Bias fell within the 95% Confidence Limit, performance was acceptable.

Potential Interferents and Non-Interfering Substances: The observed bias was compared to the Maximum Allowable Interference (MAI).

- If the observed bias was within the MAI criteria (either in a positive or negative direction), performance was acceptable.

- If the observed bias was greater than the MAI the bias was compared to the 95% Confidence Limit (two-sided) per CLSI EP07-A2. If the Claimed Bias fell within the 95% Confidence Limit, performance was acceptable.

Results demonstrate acceptable bias on the VITROS XT 7600 versus the VITROS 5600 for currently claimed interferents. The following previously untested analyte/interferent level yielded new information for a currently claimed interferent compound as a result of testing:

- 110 mmol/L Cl^-/ 4 mg/dL 4-Aminosalicylate on Cl^- MicroSlides

One additional interfering substance was identified as a result of testing:

- Triglyceride on Cl^-(s) MicroSlides

For the interferent indicated, bias profiles on the VITROS XT 7600 demonstrated equivalent magnitudes to those using the VITROS 5600, using the noted substance. The Instructions for Use (IFU) for the VITROS Cl^- assay has been updated to claim the additional interfering substances.

Conclusion

The conclusions drawn from the nonclinical tests (discussed above) demonstrate the VITROS Chemistry Products Cl- Slides, VITROS Chemistry Product CREA Slides, and VITROS Chemistry Product GLU Slides for use on the VITROS XT 7600 Integrated System are as safe, effective, and perform as well as the predicate devices. The information submitted in the premarket notification is complete and supports a substantial equivalence decision.