April 3, 2019

Ortho-Clinical Diagnostics, Inc.
Darlene Phillips
Manager, Regulatory Affairs
100 Indigo Creek Drive
Rochester, NY 14626

Re: K190520
Trade/Device Name: VITROS XT Chemistry Products GLU-Ca Slides
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: CGA, CJY
Dated: February 28, 2019
Received: March 4, 2019

Dear Darlene Phillips:

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)*
k190520

Device Name
VITROS XT Chemistry Products GLU-Ca Slides

Indications for Use *(Describe)*
For in vitro diagnostic use only
The GLU test within the VITROS XT Chemistry Products GLU-Ca Slides quantitatively measures glucose (GLU) concentration in serum, plasma, urine, and cerebrospinal fluid using VITROS 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.

The Ca test within the VITROS XT Chemistry Products GLU-Ca Slides quantitatively measures calcium (Ca) concentration in serum, plasma, and urine using VITROS XT 7600 Integrated Systems. Calcium measurements are used in the diagnosis and treatment of parathyroid disease, a variety of bone diseases, chronic renal disease and tetany (intermittent muscular contractions or spasms).

Special conditions for use statement: For prescription use only.

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

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**:** **k190520**

Submitter's Information

Ortho-Clinical Diagnostics, Inc.
100 Indigo Creek Drive
Rochester, New York 14626-5101
Phone: (585) 453-4253
Fax: (585) 453-3113

Contact Person:

Darlene J Phillips, RAC
Manager, Regulatory Affairs

Date of Preparation: February 28, 2019

Device Proprietary Name(s):

VITROS XT Chemistry Products GLU-Ca Slides

Common Names:

Glucose test
Calcium test

Classification Names

Test	Product Code	Class	Regulation Section	Panel
GLU	CGA	Class II	21 CFR 862. 1345 Glucose test system	Clinical Chemistry(75)
Ca	CJY	Class II	21 CFR 862. 1145 Calcium test system	

Predicate Device(s)

Predicate Devices	FDA 510(k) Number
VITROS Chemistry Products GLU Slides	k182072
VITROS Chemistry Products Ca Slides	k072440

Intended Use Statement(s)

VITROS XT Chemistry Products GLU-Ca Slides

Rx Only. For in vitro diagnostic use only.

The GLU test within the VITROS XT Chemistry Products GLU-Ca Slides quantitatively measures glucose (GLU) concentration in serum, plasma, urine, and cerebrospinal fluid using VITROS 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.

The Ca test within the VITROS XT Chemistry Products GLU-Ca Slides quantitatively measures calcium (Ca) concentration in serum, plasma, and urine using VITROS XT 7600 Integrated Systems. Calcium measurements are used in the diagnosis and treatment of parathyroid disease, a variety of bone diseases, chronic renal disease and tetany (intermittent muscular contractions or spasms).

Device Description

The new device, the VITROS XT Chemistry Products GLU-Ca Slides is a single device that contains both a GLU test and a Ca test side by side separated by a plastic barrier sealed within a single slide frame. In this format, individual reactions occur and test results are generated for each analyte independently of the other analyte.

For glucose measurement, a drop of patient sample is deposited on the GLU test element of the slide and is evenly distributed by the spreading layer to the underlying layers. The oxidation of sample glucose is catalyzed by glucose oxidase to form hydrogen peroxide and gluconate. This reaction is followed by an oxidative coupling catalyzed by peroxidase in the presence of dye precursors to produce a dye. The intensity of the dye is measured by reflected light. The dye system used is closely related to that first reported by Trinder.[1] The chemistry of the glucose slides has been described by Curme, et al.[2]

For calcium measurement, a drop of patient sample is deposited on the Ca test element of the slide and is evenly distributed by the spreading layer to the underlying layers. The bound calcium is dissociated from binding proteins, allowing the calcium to penetrate through the spreading layer into the underlying reagent layer. There, the calcium forms a complex with Arsenazo III dye, causing a shift in the absorption maximum. After incubation, the reflection density of the colored complex is measured spectrophotometrically. The amount of colored complex formed is proportional to the calcium concentration in the sample.

1 Trinder P. Determination of Glucose in Blood Using Glucose Oxidase with an Alternative Oxygen Receptor. Ann. Clin. Biochem. 6:24; 1969.

2. Curme HG, et al. Multilayer Film Elements for Clinical Analysis. Clin. Chem. 24:1335–1342; 1978.

Comparison to Predicate Devices

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

Summary of the technological characteristics of the device compared to the predicate device		
Device Characteristic	**New Device VITROS XT GLU-Ca Slide (New)**	**Predícate Devices VITROS GLU Slide [k182072] VITROS Ca Slide [k072440] (Current)**
Intended Use	Same for each individual test For *in vitro* diagnostic use only. The GLU test within the VITROS XT Chemistry Products GLU-Ca Slides quantitatively measures glucose (GLU) concentration in serum, plasma, urine, and cerebrospinal fluid (CSF). The Ca test within the VITROS XT Chemistry Products GLU-Ca Slides quantitatively measures calcium (Ca) concentration in serum, plasma, and urine.	For *in vitro* diagnostic use only. VITROS Chemistry Products GLU Slides quantitatively measure glucose (GLU) concentration in serum, plasma, urine, and CSF. VITROS Chemistry Products Ca Slides quantitatively measure calcium (Ca) concentration in serum, plasma, and urine.
Device Description	No Change	Multilayered, analytical element coated on a polyester support
Basic Principle	No Change	GLU Colorimetric Ca Colorimetric
Incubation time and temperature	No Change	Approximately 5 minutes 37°C (98.6° F)
Sample type	No Change	GLU Serum, plasma, urine and cerebrospinal fluid (CSF) Ca Serum, plasma and urine
Amount of Slide Reactive Ingredients per cm^2 (test)	No Change The composition of the analytical element of each test within the VITROS XT Slide will remain the same as that used in each predicate device	GLU 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. Ca Arsenazo III dye 60 µg

Summary of the technological characteristics of the device compared to the predicate device		
Device Characteristic	**New Device VITROS XT GLU-Ca Slide (New)**	**Predícate Devices VITROS GLU Slide [k182072] VITROS Ca Slide [k072440] (Current)**
Assay Range	No Change	GLU (mg/dL) Serum/plasma 20 - 625 Urine 20 – 650 CSF 20 – 650 Ca (mg/dL) Serum/plasma 1.0 - 14.0 Urine 1.0 – 17.8
Calibrators	Same	VITROS Chemistry Products Calibrator Kit 1
Controls	Same	VITROS Chemistry Products Performance Verifier I and II VITROS Chemistry Products Liquid Performance Verifier I and II
Differences		
Instrumentation	VITROS XT 7600 Integrated System	VITROS 250/350, 5,1 FS and 4600 Chemistry Systems VITROS 5600 and XT 7600 Integrated Systems
Sample volume	GLU 2.7 µL Ca 3.5 µL	GLU 6 µL Ca 10 µL

Non-Clinical Testing Analytical Performance

Method Comparison

Method Comparison testing followed CLSI Protocol EP09c, *Measurement Procedure Comparison and Bias Estimation Using Patient Samples.* Serum, urine and cerebrospinal fluid (glucose only) samples were evaluated on the VITROS XT Chemistry Products GLU-Ca Slides using the VITROS XT 7600 Integrated System and on VITROS Chemistry Products GLU Slides and VITROS Chemistry Products Ca Slides using the VITROS 5600 Integrated System. The correlation between the predicate and the new tests within the VITROS XT GLU-Ca Slides on the VITROS XT 7600 Integrated System is summarized below.

Weighted Deming regressions were performed to determine the correlation for GLU (all fluid types) and Ca (urine). Ordinary Deming regression was performed to determine the correlation between the Ca serum methods.

Summary of Method Comparison Regression Analysis DataUnits mg/dL						
Test	**N**	**Slope**	**Intercept**	**Corr. Coeff.**	**Test Range**	**Measuring range**
GLU Serum	116	0.99	-0.91	1.000	25 – 571	20 – 625
GLU Urine	103	1.01	-0.18	1.000	24-642	20 – 650
GLU CSF	149	0.98	-0.06	1.000	21-596	20 - 650
Ca Serum	112	0.99	0.04	0.999	1.4-13.9	1.0 – 14.0
Ca Urine	119	0.99	0.07	0.999	2.2-17.2	1.0 – 17.8

Precision

Precision was evaluated with patient pools and quality control materials following CLSI Protocol EP05-A3, *Evaluation of Precision Performance of Quantitative Methods; Approved Guideline—Third Edition*, using the VITROS XT Chemistry Products GLU-Ca Slides on the VITROS XT 7600 Integrated System. The test included 80 observations (2 replicates per run, 2 runs per day over 20 days) for serum and urine for the Ca test and serum, urine, and CSF for the GLU test. The long term precision analysis is summarized below.

The data presented are a representation of test performance and are provided as a guideline. Variables such as sample handling and storage, reagent handling and storage, laboratory environment, and system maintenance can affect reproducibility of test results.

GLU Serum Units (mg/dL)								
Mean Conc.	**Repeatability***		**Within Day****		**Within Lab*****		**No. of Obs.**	**No. of Days**
	SD	**CV%**	**SD**	**CV%**	**SD**	**CV%**		
42	0.3	0.6	0.4	1.0	0.4	1.0	80	20
87	0.4	0.4	0.8	0.9	0.8	0.9	80	20
105	0.5	0.4	1.0	0.9	1.0	0.9	80	20
121	0.6	0.5	1.3	1.1	1.4	1.2	80	20
292	0.9	0.3	2.4	0.8	2.6	0.9	80	20
573	2.0	0.4	5.0	0.9	5.3	0.9	80	20

GLU Urine Units (mg/dL)								
Mean Conc.	**Repeatability***		**Within Day****		**Within Lab*****		**No. of Obs.**	**No. of Days**
	SD	**CV%**	**SD**	**CV%**	**SD**	**CV%**		
26	0.3	1.2	0.5	1.8	0.5	1.9	80	20
43	0.3	0.7	0.4	1.0	0.5	1.1	80	20
44	0.4	0.8	0.5	1.0	0.5	1.1	80	20
114	0.5	0.5	0.7	0.6	0.7	0.6	80	20
292	1.5	0.5	1.7	0.6	1.7	0.6	80	20
614	1.7	0.3	2.4	0.4	2.7	0.4	80	20

GLU CSF Units (mg/dL)								
Mean Conc.	Repeatability*		Within Day**		Within Lab***		No. of Obs.	No. of Days
	SD	CV%	SD	CV%	SD	CV%		
37	0.3	0.8	0.4	1.1	0.4	1.1	80	20
38	0.3	0.8	0.5	1.2	0.5	1.2	80	20
39	0.3	0.7	0.4	1.1	0.5	1.2	80	20
87	0.4	0.4	0.6	0.7	0.6	0.7	80	20
318	1.4	0.4	1.7	0.6	2.0	0.6	80	20
644	2.7	0.4	3.5	0.6	3.6	0.6	80	20

Ca Serum Units (mg/dL)								
Mean Conc.	Repeatability*		Within Day**		Within Lab***		No. of Obs.	No. of Days
	SD	CV%	SD	CV%	SD	CV%		
2.3	0.04	1.7	0.06	2.6	0.07	2.9	80	20
6.8	0.04	0.6	0.06	0.8	0.09	1.4	80	20
8.4	0.07	0.8	0.08	0.9	0.10	1.2	80	20
8.8	0.05	0.6	0.07	0.8	0.08	0.9	80	20
11.9	0.07	0.6	0.08	0.7	0.11	1.0	80	20
12.2	0.06	0.5	0.07	0.6	0.11	0.9	80	20

Ca Urine						Units (mg/dL)		
Mean Conc.	Repeatability*		Within Day**		Within Lab***		No. of Obs.	No. of Days
	SD	CV%	SD	CV%	SD	CV%		
2.1	0.05	2.3	0.07	3.5	0.07	3.4	80	20
5.0	0.04	0.7	0.05	1.0	0.06	1.1	80	20
5.6	0.05	0.8	0.06	1.1	0.07	1.2	80	20
6.6	0.04	0.6	0.07	1.1	0.09	1.3	80	20
9.7	0.08	0.8	0.08	0.8	0.10	1.1	80	20
15.7	0.11	0.7	0.16	1.0	0.28	1.8	80	20

*Repeatability (formerly called within-run precision) was determined using two replicates per run.

**Within Day precision was determined using two runs/day with two replications per run

***Within Lab precision was determined using a single lot of slides and a single calibration

Detection Limits

Detection capability studies for the GLU and Ca tests within the VITROS XT GLU-Ca Slides were evaluated according to CLSI EP17-A2: Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures.

LoQ determination was set on pre-defined total error (TE) goals based on the Westgard model, a combination of bias and precision. The Total Error goal used to accept the LoQ for GLU was ≤ 4.8 mg/dL for serum, ≤ 3.9 mg/dL for urine and ≤ 4.6 mg/dL for CSF. The Total Error goal used to accept the LoQ for Ca was ≤ 0.15 mg/dL for serum and ≤ 0.42 mg/dL for urine.

The results of this analysis are summarized below:

	GLU (mg/dL)			**Ca (mg/dL)**	
	Serum	**Urine**	**CSF**	**Serum**	**Urine**
LOB	1.0	2.5	1.0	0.10	0.05
LOD	1.9	3.0	1.9	0.14	0.09
LOQ	15.9	13.0	15.2	0.49	0.60
Claimed LOQ	20	20	20	1.0	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 XT GLU-Ca Slides were tested on the VITROS XT 7600 Integrated System. A series of twenty proportionally related admixtures of low and high test fluids were tested to verify linearity of the GLU and Ca serum and urine tests and the GLU CSF test; each sample was tested in quadruplicate. The linearity studies support the claimed measuring ranges for the individual tests within the VITROS XT GLU-Ca Slides.

Assay	**Fluid**	**Measuring Range (mg/dL)**	**Linear Range (mg/dL)**
GLU	Serum/plasma	20-625	19.3-635.3
	Urine	20-650	15.4-776.1
	CSF	20-650	19.2-650.9
Ca	Serum/plasma	1.0-14.0	0.85-15.82
	Urine	1.0-17.8	0.75-20.67

Serum and plasma samples with values greater than the measuring range may be diluted with one part sample to one part diluent. A 7% BSA solution was found to be an acceptable diluent for the GLU test within the VITROS XT Chemistry Products GLU-Ca Slides. Isotonic saline and reagent-grade water were found to be acceptable diluents for the Ca test within the VITROS XT Chemistry Products GLU-Ca Slides.

Urine samples with values greater than the measuring range may be diluted with one part sample to one part diluent. Isotonic saline and reagent-grade water were found to be acceptable diluents for the GLU test within the VITROS XT Chemistry Products GLU-Ca Slides. Reagent-grade water was found to be an acceptable diluent for the Ca test within the VITROS XT Chemistry Products GLU-Ca Slides.

Expected Values

The expected values of the GLU and Ca tests within the VITROS XT GLU-Ca Slides are the not changed from those of the predicate assays. Each laboratory should confirm the validity of these intervals for the population it serves.

GLU Reference Interval

GLU reference intervals for serum, urine and CSF are based on external studies[1].

GLU Test Expected Values	
Serum	
Fasting adults	74-100 mg/dL
Urine	
Random	1-15 mg/dL
24 hour	< 500 mg/day*
CSF	40-70 mg/dL

* Glucose concentration (mg/dL) x 24-hour volume (dL) = mg/day.

Ca Reference Interval

Ca reference intervals are based on external studies for serum[1] and urine[2].

Ca Test Expected Values	
Serum	8.6–10.3 mg/dL
Urine — Dietary Ca Intake:	
Ca-free	5–40 mg/day*
Low to average	50–150 mg/day*
Average	100–300 mg/day*

* Calcium concentration (mg/dL) x 24-hour volume (dL) = mg/day.

Each laboratory should confirm the validity of these intervals for the population it serves.

References

1. Tietz NW. *Fundamentals of Clinical Chemistry and Molecular Diagnostics*. 7th ed. St. Louis: Elsevier; 2015.

2. Tietz NW (ed). *Fundamentals of Clinical Chemistry*. ed. 5. Philadelphia: WB Saunders; 968; 2001.

Specificity

The GLU and Ca tests within the VITROS XT Chemistry Products GLU-Ca Slides were screened for interfering substances following CLSI document EP07, Interference Testing in Clinical Chemistry. The supplemental tables in CLSI document EP37 were referenced for recommended testing concentrations for analytes and endogenous substances that may interfere in clinical chemistry measurement procedures.

Point estimates of the effects of potential interferents on VITROS XT GLU-Ca Slides were made using the paired difference method. Dose-response analysis was conducted to characterize the degree of interference for each substance that interfered at the initial EP37 level screening test, and expected bias was reported at the lowest test level which did not meet acceptance criteria for bias as shown in the product claims.

GLU Test

For the GLU test within VITROS XT GLU-Ca Slides, interference was observed for three (3) substances with serum. The substances listed in the table, when tested at the concentrations indicated, caused the bias shown. The bias is an estimate of the maximum bias observed.

It is possible that other interfering substances may be encountered. These results are representative; however, your results may differ somewhat due to test-to-test variation. The degree of interference at concentrations other than those listed might not be predictable.

GLU Serum Known Interfering Substances			
Interferent	**Interferent Concentration**	**Glucose Concentration (mg/dL)**	**Bias (mg/dL)**
Glutathione	92 mg/dL	73	-10.4
Hemoglobin	1000 mg/dL	79	7.6
Total Protein	15 g/dL	74	8.8
		217	20.4

- When using samples with visible hemolysis (Hb > 200 mg/dL), there may be a negative bias due to catalase released from the lysis of red blood cells. The VITROS XT Systems can perform Sample Indices using the MicroSensor module, and the GLU result from samples with visible hemolysis will be flagged with H (Hemolysis).
- Elevated lipids may limit diffusion of oxygen to the reactants. Dilute grossly lipemic samples twofold before analysis.

Interference was observed with four (4) substances tested in urine.

GLU Urine Known Interfering Substances			
Interferent	**Interferent Concentration**	**Glucose Concentration (mg/dL)**	**Bias (mg/dL)**
Ascorbic acid	50 mg/dL	31	-14.0
	13 mg/dL	171	-13.7
Dextran	7.5 g/dL	31	8.0
	2.5 g/dL	169	14.4
Hemoglobin	250 mg/dL	33	8.5
N-Acetylcysteine	25 mg/dL	166	-14.0

One (1) substance was tested and found to cause interference in cerebrospinal fluid (CSF).

GLU CSF Known Interfering Substances			
Interferent	**Interferent Concentration**	**Glucose Concentration (mg/dL)**	**Bias (mg/dL)**
Hemoglobin	250 mg/dL	47	5.0
	1000 mg/dL	69	12.1
		87	10.2

For the GLU test within VITROS XT GLU-Ca Slides, no interference was observed for seventy-nine (79) substances tested in serum, bias < 7.0 mg/dL at approximately 80 mg/dL glucose and bias < 14 mg/dL at approximately 200 mg/dL glucose. No interference was observed for eighteen (18) substances tested in urine, bias < 7.0 mg/dL at approximately 30 mg/dL glucose and bias < 11.9 mg/dL at approximately 170 mg/dL glucose.

Ca Test

For the Ca test within VITROS XT GLU-Ca Slides, interference was observed for seven (7) substances with serum. The substances listed in the table, when tested at the concentrations indicated, caused the bias shown. The bias is an estimate of the maximum bias observed.

It is possible that other interfering substances may be encountered. These results are representative; however, your results may differ somewhat due to test-to-test variation. The degree of interference at concentrations other than those listed might not be predictable.

Ca Serum Known Interfering Substances			
Interferent	**Interferent Concentration**	**Calcium Concentration (mg/dL)**	**Bias (mg/dL)**
Cefoxitin	663 mg/dL	7.7	0.28
		11.3	0.50
Cholesterol	525 mg/dL	6.3	0.34
	625 mg/dL	9.5	0.34
Gadodiamide	86 mg/dL	7.4	0.35
Hemoglobin	1000 mg/dL	8.3	-0.30
Sodium	391 mg/dL	7.4	0.35
		11.1	0.52
Sorbitol	1800 mg/dL	11.9	-0.37
Total Protein	15 g/dL	12.1	-0.45

For the Ca test within VITROS XT GLU-Ca Slides, no interfering compounds were observed for urine. For the Ca test within VITROS XT GLU-Ca Slides, no interference was observed for seventy-five (75) substances tested in serum, bias < 0.23 mg/dL at approximately 8 mg/dL calcium and bias < 0.27 mg/dL at approximately 12 mg/dL calcium. No interference was observed for twenty (20) substances tested in urine, bias < 0.79 mg/dL at approximately 5 mg/dL calcium and bias < 1.2 mg/dL at approximately 12 mg/dL calcium.

Other Limitations

Keeping the sample in an open container at room temperature may increase the reported calcium concentration by up to 0.4 mg/dL. Changes are due to the loss of carbon dioxide, which results in an increase in pH of the specimen. The increase in pH is minimized by anaerobic handling procedures followed by prompt analysis. Adherence to these procedures is especially important for pediatric samples where the sample volume is small.

Certain drugs and clinical conditions are known to alter glucose and calcium concentrations *in vivo.* For additional information, refer to one of the published summaries.

Conclusion

The conclusions drawn from the nonclinical tests (discussed above) demonstrate the VITROS XT Chemistry Products GLU-Ca 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.