August 9, 2023

Ortho Clinical Diagnostics
Declan Hynes
Senior Regulatory Affairs Manager
Felindre Meadows Pencoed
Bridgend, CF35 5PZ
United Kingdom

Re: K231525
Trade/Device Name: VITROS CA 19-9
Regulation Number: 21 CFR 866.6010
Regulation Name: Tumor-Associated Antigen Immunological Test System
Regulatory Class: Class II
Product Code: NIG
Dated: May 26, 2023
Received: May 26, 2023

Dear Declan Hynes:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Ying Mao -S

Ying Mao, Ph.D.
Branch Chief
Division of Immunology and Hematology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231525

Device Name
VITROS Immunodiagnostic Products CA 19-9TM Reagent Pack

Indications for Use *(Describe)*
For in vitro diagnostic use only.

For the quantitative measurement of 1116-NS-19-9 defined antigen in human serum and plasma (EDTA or heparin), using the VITROS 5600 Integrated System. The VITROS CA 19-9 test is to be used to aid in the management of patients diagnosed with cancers of the exocrine pancreas. The VITROS CA 19-9 test can be used to monitor the disease status in patients with confirmed pancreatic cancer who show measurable CA 19-9 values over the course of their disease. Serial CA 19-9 test results should be used in conjunction with all other available clinical and laboratory data before a medical decision is determined.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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: K231525

Submitter's Information

Ortho-Clinical Diagnostics Inc.

Felindre Meadows,

Pencoed,

UK CF35 5PZ Phone: +44 07505
370257

Fax: (585) 453-3368
Contact Person: Declan Hynes

Preparation Date

August 01, 2023

Device Proprietary Name(s)

VITROS Immunodiagnostic Products CA 19-9™ Reagent Pack

Common Name(s) VITROS CA19-9 Assay

Classification Names

Product Code	Class	Regulation Section	Panel
NIG	II	21 CFR 866.6010 Tumor-associated antigen immunological test system	Immunology

Predicate Device(s)

Predicate Device	FDA 510(k) Number
VITROS Immunodiagnostic Products CA 19-9 Assay	K052889

Device Description

The VITROS Immunodiagnostic Products CA 19-9 assay (test) is performed using the VITROS Immunodiagnostic Products CA 19-9™ Reagent Pack and VITROS CA 19-9 Calibrators on the VITROS 5600 System.

An immunometric immunoassay technique is used, which involves the simultaneous reaction of 1116-NS-19-9 defined antigen present in the sample with a microwell coated with biotinylated Antibody (Mouse monoclonal anti-1116-NS-19-9 defined antigen) bound to Streptavidin. In a second incubation a Horseradish Peroxidase (HRP)- labelled antibody conjugate (Mouse monoclonal anti-1116-NS-19-9 defined antigen) binds to the immobilized 1116-NS-19-9 defined antigen. Unbound materials are removed by washing.

The bound HRP conjugate is measured by a luminescent reaction. A reagent containing luminogenic substrates (a luminol derivative and a peracid salt) and an electron transfer agent, is added to the wells. The

HRP in the bound conjugate catalyzes the oxidation of the luminol derivative, producing light. The electron transfer agent (a substituted acetanilide) increases the level of light produced and prolongs its emission. The light signals are read by the system. The amount of conjugate bound is directly proportional to the concentration of 1116-NS-19-9 defined antigen present in the sample.

VITROS Immunodiagnostic Products CA 19-9™ Reagent Pack contains:

1 reagent pack containing:

- 100 coated wells (antibody, mouse monoclonal anti-1116-NS-19-9 defined antigen, binds ≥49 U 1116-NS-19-9 defined antigen/well)
- 13.4 mL assay reagent (buffer containing bovine serum, bovine gamma globulin and antimicrobial agent)
- 20.0 mL conjugate reagent (HRP-mouse monoclonal anti-1116-NS-19-9 defined antigen, binds ≥326 U 1116-NS-19-9 defined antigen/mL) in buffer with bovine serum albumin, bovine gamma globulin and antimicrobial agent.

VITROS CA 19-9 Calibrator contains:

- 1, 2, and 3 (OC 1116-NS-19-9 defined antigen in buffer with bovine serum albumin and antimicrobial agent, 1.75 mL); nominal values 15; 60 and 700 U 1116-NS-19-9 defined antigen/mL
- 24 calibrator bar code labels (8 for each calibrator)

Intended Use Statement(s):

Rx ONLY

For *in vitro* diagnostic use only.
For the quantitative measurement of 1116-NS-19-9 defined antigen in human serum and plasma (EDTA or heparin), using the VITROS 5600 Integrated System. The VITROS CA 19-9 test is to be used to aid in the management of patients diagnosed with cancers of the exocrine pancreas. The VITROS CA 19-9 test can be used to monitor the disease status in patients with confirmed pancreatic cancer who show measurable CA 19-9 values over the course of their disease. Serial CA 19-9 test results should be used in conjunction with all other available clinical and laboratory data before a medical decision is determined.

Comparison to Predicate Devices

The following tables provide a summary of the key features of the new device assessed against the predicate.

Device Characteristic	Predicate Device VITROS Immunodiagnostic Products CA 19-9 Assay, K052889, cleared 20 December 2005	Modified Device VITROS Immunodiagnostic Products CA 19-9™ Reagent Pack
Intended Use	Rx ONLY For in vitro diagnostic use only. For the quantitative measurement of 1116-NS-19-9 defined antigen concentration in human serum and plasma (EDTA or heparin) using the VITROS ECi/ECiQ/3600 Immunodiagnostic Systems and the VITROS 5600/XT 7600 Integrated Systems. The VITROS CA 19-9 assay is to be used as an aid in management of patients diagnosed with caners of the exocrine pancreas. The VITROS CA 19-9 test can be used to monitor disease status in patients with confirmed pancreatic cancer who show measurable CA 19-9 values over the course of their disease. Serial CA 19-9 test results should be used in conjunction with other clinical and laboratory data before a medical decision is determined.	Rx ONLY For in vitro diagnostic use only. For the quantitative measurement of 1116-NS-19-9 defined antigen concentration in human serum and plasma (EDTA or heparin) using the VITROS 5600 Integrated System. The VITROS CA 19-9 test is to be used to aid in the management of patients diagnosed with cancers of the exocrine pancreas. The VITROS CA 19-9 test can be used to monitor the disease status in patients with confirmed pancreatic cancer who show measurable CA 19-9 values over the course of their disease. Serial CA 19-9 test results should be used in conjunction with all other available clinical and laboratory data before a medical decision is determined.
Assay Principle	Immunometric.	Same.
Antibody	Mouse Monoclonal anti-1116-NS-19-9 antigen.	Same.
Sample Type	Serum and Plasma.	Same.
Sample Volume	35 µL.	Same.

Traceability	Calibration of the VITROS CA 19-9 test is traceable to in-house reference calibrators which have been value assigned to correlate to another commercially available test.	Same.
Measuring Range	1.4–1000 (U/mL)	Same.
Detect on Limit	LOB: 1.05 (U/mL) LOD: 1.4 (U/mL) LOQ: 1.4 (U/mL)	LOB: Same. LOD: Same. LOQ: Same
Calibrator Levels	3.	Same.

Differences:

Basic Principle	Sandwich immunoassay	Sandwich immunoassay. In the modified CA 19-9 assay, the mouse anti-1116-NS-19-9 has been removed from the Biotin Reagent and coated directly onto the well. The modification to allow the biotinylated antibody capture conjugate to be pre- bound to the well, eliminates the risk of biotin interference.
Instrumentation	VITROS 5600 Integrated System VITROS XT7600 Integrated System VITROS 3600 Immunodiagnostic System VITROS ECi/ECiQ Immunodiagnostic System	VITROS 5600 Integrated System

Nonclinical Performance

Several nonclinical tests were performed.

Stability Studies

Long term stability and on-board storage performance was evaluated consistent with methods based on CLSI EP25-A.

Long Term Stability: Four runs have been performed on each of 3 Lots at each time-point, monthly intervals, data supports a 20 week shelf-life.

On-board Stability: Three Lots of the VITROS CA19-9 assay were stored opened refrigerated for up to 12 weeks. Four runs were performed on the each Lot at each time-point for fresh and open, all result were acceptable and support the current claim of 8 weeks on-board stability.

Precision

Precision was evaluated on the VITROS 5600 Integrated System consistent with CLSI document EP05-A3, *Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline—Third Edition.* Six (6) precision fluids, covering the analytical measuring interval, were evaluated for performance. For one reagent lot, two (2) replicates of each precision fluid were run on two (2) occasions per day for twenty (20) days, for a total of 80 data points per fluid.

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.

VITROS System	Units = U/mL					No. of Obs.	No. of Days
	Mean CA 19-9 Conc.	Repeatability*		Within Lab**			
		SD	%CV	SD	%CV		
5600	29.0	0.5	1.8%	1.9	6.6%	80	20
	107	2.0	1.9%	6.3	5.9%	80	20
	223	4.4	2.0%	9.2	4.1%	80	20
	301	5.8	1.9%	14.0	4.6%	80	20
	708	12.1	1.7%	27.6	3.9%	80	20
	6.7	0.1	2.2%	0.3	4.2%	80	20

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

**Within Lab precision was determined using a single reagent lot and a single calibration.

Detection Capability

Detection studies for the VITROS CA 19-9 Assay were evaluated on the VITROS 5600 Integrated System consistent with CLSI document EP17-A2, *Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline* – Second Edition. Four endogenous fluids containing no measurable 1116-NS-19-9 defined antigens (CA19-9) were used for determining the LoB. The study design was 2 replicates per run, 2 runs per day over 5 test days = 20 reps per test fluid x 4 fluids = 80 replicates x 3 lots = 240 total replicates

Five samples were used for establishing the LoD, which were targeted at 1 to 5 times the LoB

concentration. The LoD samples were admixtures of serum samples containing endogenous CA 19-9 to achieve the approximate target CA 19-9 concentrations. The LoD fluids were used to determine the LoQ. All samples were run using three reagent lots on one VITROS 5600 System,

6 replicates per run, 2 runs per day over 5 test days = 60 reps per fluid x 5 fluids = 300 replicates x 3 lots = 900 total replicates.

The Limit of Detection (LoD) for the VITROS CA 19-9 test is 1.4 U/mL, determined consistent with CLSI document EP17-A2[1]. The Limit of Quantification (LoQ) for the VITROS CA19-9 test was designed to be less than or equal to 1.4 U/mL at 20%CV. The existing LoB product claim of 1.05 U/mL has been verified.

Linearity

Linearity was established in accordance with the CLSI document EP06 2nd Edition. The linearity test panel was comprised of 16 levels, five replicates of each linearity level were run on three reagent lots on one VITROS 5600 Integrated System over 2 days.

			Slope		Intercept		
Lot	**Dilution Range**	**% Recovery**	**Estimate**	**95% CI**	**Estimate**	**95% CI**	**R^2**
9995	0.9 to 1152	93.0% to 125%	0.973	0.957 to 0.989	0.145	0.103 to 0.186	0.999

Weighted Least Squares Regression						
Level	**%HP**	**Measured Result**	**Predicted Result**	**Deviation from Linearity**	**Allowable Deviation from Linearity**	**Pass / Fail**
		(U/mL)	**(U/mL)**		**(±)**	
1	0.00	0.861	0.981	-12.3%	15.0%	Pass
2	0.03	1.516	1.328	14.1%	15.0%	Pass
3	0.05	1.59	1.52	5.0%	15.0%	Pass
4	0.10	2.35	2.08	13.0%	15.0%	Pass
5	0.50	6.81	6.60	3.1%	15.0%	Pass
6	1.00	12.2	12.1	0.3%	15.0%	Pass
7	2.99	33.5	34.5	-2.8%	15.0%	Pass
8	5.01	54.6	57	-4.3%	15.0%	Pass
9	10	108	113	-4.5%	15.0%	Pass
10	30	332	337	-1.5%	15.0%	Pass
11	40	441	449	-1.7%	15.0%	Pass
12	50	557	561	-0.6%	15.0%	Pass
13	60	668	672	-0.6%	15.0%	Pass
14	80	904	896	0.8%	15.0%	Pass
15	95	1074	1064	0.9%	15.0%	Pass
16	100	1152	1121	2.8%	15.0%	Pass
Linearity Interval				0.9 to 1152 U/mL		

Linearity/Measuring Range

VITROS System	**Measuring (Reportable) Range**
5600	1.4–1000 U/mL

Matrix Comparison

Serum and plasma (Li-Hep and EDTA) specimen matrices was determined to be equivalent. The results met the acceptance criteria for the comparison between serum and plasma (Li-Hep and EDTA) specimens spanning the expected measuring interval. Based on the analysis serum and plasma (Li-Hep and EDTA) are suitable specimen matrices for use with the VITROS CA 19-9 assay.

Specimens Recommended

- Serum and Plasma

Specimens Not Recommended

- Do not use turbid specimens. Turbidity in specimens may affect test results.

VITROS 5600 System		
Ordinary Deming	**Li-Hep**	**EDTA**
Slope	0.97	0.98
Correlation Coefficient (r)	0.99	1.00
n	41	41
Pass/Fail Status	Pass	Pass

Analytical Specificity

Known Interferences

The VITROS CA 19-9 assay was screened for interfering substances at CA 19-9 concentrations of approximately 5.0 U/mL and 50.0 U/mL following CLSI EP07[1] and EP37.[2] The substances listed in the table demonstrated observed bias of ≥ 10% when tested at the concentrations shown.

For substances that were tested and did not interfere, refer to "Substances that do not Interfere."

Interferent	Interferent Concentration		Analyte Conc.* (U/mL)	Bias %**
Hemoglobin	1000 mg/dL	0.155 mmol/L	7.1	190.1
			45.2	30.5
	125 mg/dL	0.0194 mmol/L	47.5	0.8
	100 mg/dL	0.0155 mmol/L	6.1	2.0
Rheumatoid Factor	1035 U/mL	N/A	5.0	27.4
	981 U/mL		43.4	2.8
	900 U/mL		32.5	5.2
	199 U/mL		5.0	5.2

*Average test concentration of replicate determinations using 3 different lots of reagent, on the VITROS 5600 platform

**Estimate of the average difference observed

Substances that do not Interfere

The substances listed in the table below were tested with the VITROS CA 19-9 assay following CLSI EP07[1] and EP37[2] and found not to cause bias > 10% at CA 19-9 concentrations of approximately 5.0 U/mL and 50 U/mL at the test concentrations shown.

Substance	Concentration	
	Conventional Units	SI Units
Acetaminophen	50 mg/dL	3.3 mmol/L
N-Acetylcysteine	15.0 mg/dL	0.919 mmol/L
Acetylsalicylic acid	50 mg/dL	2.78 mmol/L
Alpha-tocopherol	6.45 mg/dL	0.150 mmol/L
Amoxicillin	5.40 mg/dL	0.148 mmol/L
Ascorbic acid	300 mg/dL	17.0 mmol/L
Bilirubin, conjugated	40 mg/dL	0.475 mmol/L
Bilirubin, unconjugated	40 mg/dL	0.684 mmol/L
Biotin	0.351 mg/dL	0.014 mmol/L
Cefoxitin sodium	695 mg/dL	15.5 mmol/L
Cetuximab	70.5mg/dL	0.00464 mmol/L
Cholecalciferol (D3)	19.2 µg/dL	0.499 µmol/L
Cholesterol, total	400 mg/dL	10.3 mmol/L
Cisplatin	5.7 mg/dL	0.19 mmol/L
Codeine	0.141 mg/dL	0.005 mmol/L
Cotinine	0.24 mg/dL	0.014 mmol/L
Coumadin	1.4 mg/dL	0.042 mmol/L
Cyclophosphamide	54.9 mg/dL	1.97 mmol/L
Cytarabine	3 mg/dL	0.123 mmol/L
Dextran 40	2400 mg/dL	0.600 mmol/L
Dextromethorphan	0.00156 mg/dL	0.057 µmol/L
Doxorubicin hydrochloride	4 mg/dL	0.053 mmol/L
Enoxaparin - Low molecular weight Heparin	360 U/dL	N/A
Ethanol	600 mg/dL	130 mmol/L
Eribulin	1.12 µg/mL	0.00136 mmol/L
5-Fluorouracil	39 mg/dL	3.0 mmol/L
Furosemide	1.59 mg/dL	0.048 mmol/L
Gemcitabine	38.2 mg/dL	1.28 mmol/L
HAMA (Human Anti-Mouse Antibodies)	800 µg/L	0.053 µmol/L
Hydralazine	1.44 mg/dL	0.073 mmol/L

Substance	Concentration	
	Conventional Units	SI Units
Hydrocodone	0.0072 mg/dL	0.241 µmol/L
Ibuprofen	40 mg/dL	1.94 mmol/L
Intralipid	2000mg/dL	0.0192 mol/L
Leucovorin	11.4 mg/dL	0.386 mmol/L
Levothyroxine	0.0429 mg/dL	0.552 µmol/L
Loratadine	0.0087 mg/dL	0.227 µmol/L
Megestrol Acetate	2.26 µg/mL	0.0058 mmol/L
Methotrexate	136 mg/dL	3.0 mmol/L
Mitomycin C	300 µg/dL	0.009 mmol/L
Morphine	0.780 mg/dL	0.010 mmol/L
Naproxen	36.0 mg/dL	1.56 mmol/L
Omeprazole	0.840 mg/dL	0.024 mmol/L
Paclitaxel	6.7 mg/dL	0.080 mmol/L
Phenytoin	6.00 mg/dL	0.238 mmol/L
Prednisone	0.010 mg/dL	0.280 µmol/L
Salicylic acid	2.86 mg/dL	0.207 mmol/L
Streptozocin	114 mg/dL	4.30 mmol/L
Tamoxifen	51.9 ug/dL	1.40 µmol/L
Theophylline	6.0 mg/dL	0.333 mmol/L
Total Protein	15 g/dL	N/A
Triglycerides, total	3000 mg/dL	33.8 mmol/L
Vancomycin hydrochloride	12.3 mg/dL	0.083 mmol/L
Vinblastine	0.0084 mg/dL	0.092 µmol/L
Vincristine	0.00162 mg/dL	0.0176 µmol/L
Vinorelbine	0.19 mg/dL	0.002 mmol/L

N/A = Not applicable, alternate units not available

Dilution

The dilution recovery and dilution imprecision product requirements were met for the VITROS Immunodiagnostic Products CA 19-9 Reagent. Serum or plasma (EDTA or heparin) samples with concentrations greater than the measuring range may be automatically diluted on the system up to 20-fold (1 part sample with 19 parts diluent) by the VITROS 5600 Integrated System with the VITROS High Sample Diluent B Reagent Pack prior to test. Refer to the VITROS High Sample Diluent B Reagent Pack instructions for use. The 20-fold dilution has been demonstrated on samples with a concentration up to 10,000 U/mL.

Expected Values

Adult Reference Interval

The adult reference interval was verified following CLSI document EP28-A3c *Defining,*

Establishing, and Verifying Reference Intervals in the Clinical Laboratory; Approved Guideline – Third Edition.

Unit (U/L)
≤37 U/mL

The number of test results from 60 normal blood donors that fell outside the reference limit of >37 U/mL are shown in Table 1, for each reagent lot and instrument combination. As no more than 10% of the test results were outside the limit, the expected values claim of the current VITROS CA 19-9 will be transferred to the updated VITROS CA 19-9 assay.

Table 1: Test results for the modified VITROS CA 19-9 assay

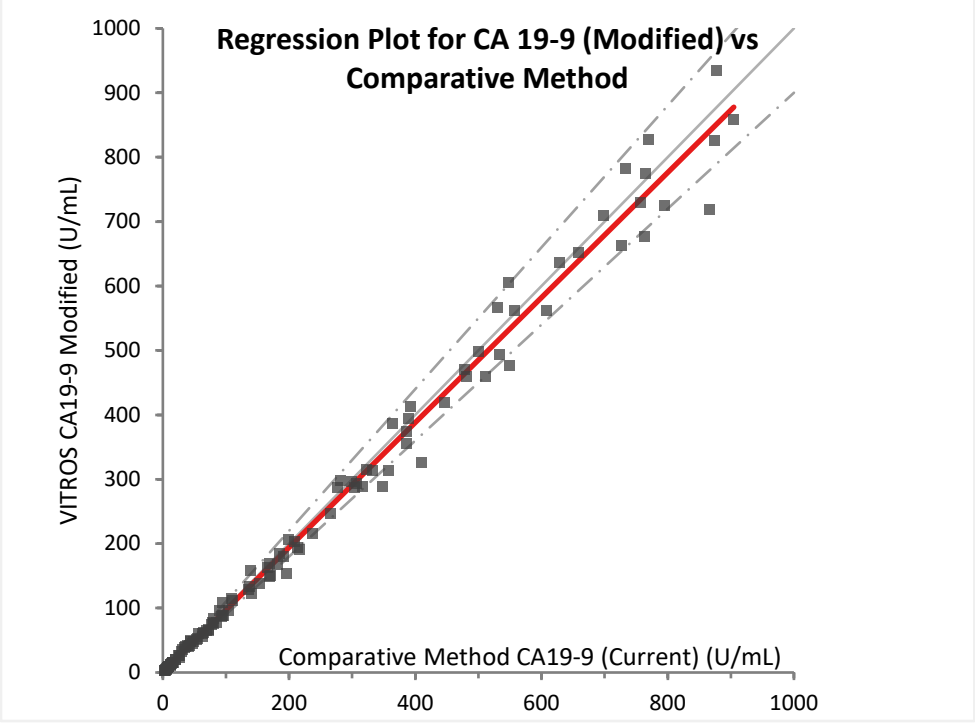
Normal Subjects	N	≤37 U/mL	37.1-70 U/mL	>70 U/mL
VITROS 5600	60	57	2	1

Traceability of Calibration

Calibration of the VITROS CA 19-9 assay is traceable to in-house reference calibrators which have been value assigned to correlate to another commercially available test.

Method Comparison

Accuracy was evaluated consistent with CLSI document EP09. The plot and table show the results of a method comparison study using patient serum samples analyzed on the VITROS 5600 Integrated System compared with those analyzed using the VITROS CA 19-9 assay. The relationship between the 2 methods was determined by Weighted Deming regression.



Single Lot Analyses	n	Sample Range (U/mL)		Slope 95% (Confidence Interval)	Intercept 95% (Confidence Interval)	R^2
VITROS 5600 Modified CA19-9 vs Comparative Method VITROS CA19-9	118	2.8	934	0.97 (0.95-0.99)	0.15 (-0.03-0.32)	0.989

Conclusion

The conclusions drawn from the nonclinical tests (discussed above) demonstrate the VITROS Immunodiagnostic Products CA 19-9 Assay is as safe, effective, and performs as well as the cleared predicate device. The information submitted in the premarket notification is complete and supports a substantial equivalence decision.