December 12, 2022

Ortho Clinical Diagnostics
Rebecca Lewis
Senior Regulatory Affairs Associate
Felindre Meadows
Pencoed, Bridgend CF35 5PZ
United Kingdom

Re: K221355
Trade/Device Name: VITROS Immunodiagnostic Products CA 125 II Reagent Pack
Regulation Number: 21 CFR 866.6010
Regulation Name: Tumor-Associated Antigen Immunological Test System
Regulatory Class: Class II
Product Code: LTK
Dated: April 27, 2022
Received: May 10, 2022

Dear Rebecca Lewis:

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)*
K221355

Device Name
VITROS Immunodiagnostic Products CA 125 II Reagent Pack

Indications for Use *(Describe)*
For the quantitative measurement of OC 125 defined antigen concentration in human serum and plasma (EDTA or heparin) using the VITROS 5600 Integrated System. The VITROS CA 125 II assay is to be used as an aid in monitoring response to therapy for patients with epithelial ovarian cancer. Serial testing for patient CA 125 assay concentrations should be used in conjunction with other clinical methods used for monitoring ovarian cancer.

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: K221355.

Submitter's Information

Ortho-Clinical Diagnostics Inc.

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Contact Person: Rebecca Lewis

Preparation Date

December 12, 2022

Device Proprietary Name(s)

VITROS® Immunodiagnostic Products CA 125 II Reagent Pack

Common Name(s) VITROS CA125 Reagent Pack

Classification Names

Product Code	Class	Regulation Section	Panel
LTK	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 125 II Reagent Pack	K983875

Device Description

The VITROS Immunodiagnostic Products CA 125 II Reagent Pack (test) is performed using the VITROS CA 125 II Reagent Pack and VITROS CA 125 II Calibrators on the VITROS 5600 System.

An immunometric immunoassay technique is used, which involves the reaction of OC 125 present in the sample with a microwell coated with biotinylated Antibody (Mouse monoclonal anti-OC 125) bound to Streptavidin, and a Horseradish Peroxidase (HRP)-labelled antibody conjugate (Mouse monoclonal anti- OC 125). Unbound (HRP)-labeled anti-OC 125 antibody conjugate is 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 OC 125 present in the sample.

VITROS CA 125 II Reagent Pack contains:

1 reagent pack containing:

- 100 coated wells (antibody, mouse monoclonal anti-OC 125 defined antigen, binds >32.5 U OC 125 defined antigen/well)
- 9.4 mL assay reagent (buffer containing bovine serum albumin, bovine gamma globulin and antimicrobial agent)
- 9.4 mL conjugate reagent (HRP-mouse monoclonal anti-OC 125 defined antigen, binds ≥542 U OC 125 defined antigen/mL) in buffer with bovine serum albumin, bovine gamma globulin and antimicrobial agent.

VITROS CA 125 II Calibrator contains:

- 1 set of VITROS CA 125 II Calibrators 1, 2, and 3 (OC 125 defined antigen in buffer with bovine serum albumin and antimicrobial agent, 1.75 mL); nominal values 24.0; 130 and 875 U OC 125 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 OC 125 defined antigen concentration in human serum and plasma (EDTA or heparin) using the VITROS 5600 integrated System. The VITROS CA 125 II assay is to be used as an aid in monitoring response to therapy for patients with epithelial ovarian cancer. Serial testing for patient CA 125 assay concentrations should be used in conjunction with other clinical methods used for monitoring ovarian cancer.

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 125 II Reagent Pack, K983875, cleared 14 May 1999	Modified Device VITROS Immunodiagnostic Products CA 125 II Reagent Pack
Intended Use	Rx ONLY For in vitro diagnostic use only. For the quantitative measurement of OC 125 defined antigen concentration in human serum and plasma (EDTA or heparin) using the VITROS 5600 Integrated System. The VITROS CA 125 II assay is to be used as an aid in monitoring response to therapy for patients with epithelial ovarian cancer. Serial testing for patient CA 125 assay concentrations should be used in conjunction with other clinical methods used for monitoring ovarian cancer.	Rx ONLY For in vitro diagnostic use only. For the quantitative measurement of OC 125 defined antigen concentration in human serum and plasma (EDTA or heparin) using the VITROS 5600 Integrated System. The VITROS CA 125 II assay is to be used as an aid in monitoring response to therapy for patients with epithelial ovarian cancer. Serial testing for patient CA 125 assay concentrations should be used in conjunction with other clinical methods used for monitoring ovarian cancer.
Assay Principle	Immunometric.	Same.
Antibody	Mouse Monoclonal anti-OC 125 antigen.	Same.
Sample Type	Serum and Plasma.	Same.
Sample Volume	25 µL.	Same.
Traceability	Calibration of the VITROS CA 125 II test is traceable to in-house reference calibrators which have been value assigned to correlate to another commercially available test.	Same.
Measuring Range	5.5–1000 (U/mL)	Same.

Detect on Limit	LOB: 2.9 (U/mL) LOD: 5.5 (U/mL)	LOB: Same. LOD: Same. LOQ: 5.5 (U/mL)
Calibrator Levels	3.	Same.
Instrumentation	VITROS 5600 Integrated System	Same.

Nonclinical Performance

Several nonclinical tests were performed.

Precision

Precision was evaluated consistent with CLSI document EP05-A3, *Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline—Third Edition.*
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.

Sample	Mean	Within-Run (Repeatability)		Between-Run		Within-Day		Between-Day		Between-Lot		Total	
		SD	% CV	SD	% CV	SD	% CV	SD	% CV	SD	% CV	SD	% CV
1	9.09	0.09	1.0	0.08	0.9	0.15	1.6	0.18	1.9	0.00	0.0	0.21	2.4
2	29.5	0.24	0.8	0.25	0.8	0.39	1.3	0.43	1.4	0.06	0.2	0.55	1.9
3	105	1.04	1.0	0.87	0.8	1.56	1.5	1.30	1.2	0.79	0.8	2.04	1.9
4	268	2.06	0.8	2.85	1.1	3.86	1.4	2.81	1.1	1.33	0.5	4.70	1.8
5	401	3.02	0.8	4.92	1.2	6.28	1.6	4.30	1.1	1.50	0.4	7.35	1.8
6	767	6.90	0.9	5.92	0.8	9.91	1.3	6.25	0.8	4.02	0.5	11.74	1.5

Detection Capability

Detection studies for the VITROS CA 125 II Reagent were evaluated consistent with CLSI document EP17-A2, *Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline* – Second Edition.

The Limit of Detection (LoD) for the VITROS CA 125 II test is 5.5 U/mL, determined consistent with CLSI document EP17. The Limit of Quantitation (LoQ) for the VITROS CA

125 II test was designed to be less than or equal to 5.5 U/mL at 20% CV. The observed LoQ at 20% CV was determined to be 0.8 U/mL, consistent with CLSI document EP17. The claimed LoQ is set at 5.5 U/mL.

Linearity

Linearity studies were performed according to CLSI document *Evaluation of Linearity of Quantitative Measurement Procedures*. 2nd ed. CLSI guideline EP06. Linearity testing fluids covering the measuring range were prepared from mixtures of low and high pools. Four replicates were collected from each level in the panel using three reagent lots of VITROS Immunodiagnostics Products CA125 II Reagent were tested on the VITROS 5600 Integrated System. Data for one lot, 9991 is presented. The VITROS CA 125 II Reagent was linear over the measuring range for the VITROS 5600 Integrated System for all reagent lots tested. The regression analysis and results of the study that established the linearity interval are shown in the Tables below.

VITROS System Name	VITROS System Number	Reagent Lot	Linearity Panel Levels used	LLLI (IU/mL)	ULLI (IU/mL)
VITROS 5600	56000118 (PM118)	9991	2 through 15	3.6	1288

			Slope		Intercept		
Lot	**Dilution Range**	**% Recovery**	**Estimate**	**95% CI**	**Estimate**	**95% CI**	**R^2**
9991	3.6 to 1288	80.0% to 101%	0.992	0.985 to 0.999	-0.932	-1.075 to -0.788	1.000

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 125 II 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	0.984	0.990
95% CI (Slope)	0.980 to 0.988	0.984 to 0.995
Intercept	0.160	0.162
95% CI (Intercept)	-0.019 to 0.338	-0.100 to 0.424
Correlation Coefficient (r)	1.000	1.000
n	49	49
Pass/Fail Status	Pass	Pass

Analytical Specificity

Known Interferences

The VITROS CA 125 II assay was screened for interfering substances at CA 125 II concentrations of approximately 10.0 U/mL and 50.0 U/mL following EP07 3rd ed – Interference Testing in Clinical Chemistry and EP37 1st ed – Supplemental Tables for Interference Testing in Clinical Chemistry. Commonly encountered substances were tested. 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	10.0	12.6
			45.9	4.8
	750 mg/dL	0.116 mmol/L	9.6	7.8
Rheumatoid Factor	1043 U/mL	N/A	11.4	28.3
	1063 U/mL		49.7	3.2
	975 U/mL		30.6	8.3
	267 U/mL		9.6	8.2
Total Protein	15.8 g/dL	N/A	10.0	11.3
	16.3 g/dL		48.4	-0.4
	11.5 g/dL		9.5	5.6

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

**Estimate of the average difference observed.

These results are representative. It is possible that other interfering substances may be encountered in the patient population. The degree of interference at concentrations other than those listed might not be predictable.

Substances that do not Interfere

The substances listed in the table below were tested with the VITROS CA 125 II test following CLSI EP07and EP37 and found not to cause bias > 10% at CA 125 II concentrations of approximately 10 U/mL and 50 U/mL at the test concentrations shown.

Substance	Concentration	
Acetaminophen	20.0 mg/dL	1.32 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
Bevacizumab	24.0 mg/dL	0.002 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
Carboplatin	15.0 mg/dL	0.404 mmol/L
Cefoxitin sodium	695 mg/dL	15.5 mmol/L
Chlorpromazine	1.0 mg/dL	0.028 mmol/L
Cholecalciferol (D3)	19.2 µg/dL	0.499 µmol/L
Cholesterol, total	400 mg/dL	10.3 mmol/L
Cisplatin	100 mg/dL	3.33 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
Dexamethasone	135 µg/dL	0.003 mmol/L
Dextran 40	2400 mg/dL	0.600 mmol/L
Dextromethorphan	0.00156 mg/dL	0.057 µmol/L
Dimenhydrinate	1.0 mg/dL	0.021 mmol/L
Diphenhydramine	1.0 mg/dL	0.039 mmol/L
Docetaxel	1.326 mg/dL	0.015 mmol/L
Doxorubicin hydrochloride	75 µg/dL	0.001 mmol/L
Enoxaparin - Low molecular weight Heparin	360 U/dL	N/A
Ethanol	600 mg/dL	130 mmol/L
Etoposide	6.0 mg/dL	0.102 mmol/L

5-Fluorouracil	9.76 mg/dL	0.750 mmol/L
Furosemide	1.59 mg/dL	0.048 mmol/L
Gemcitabine	7.0 mg/dL	0.234 mmol/L
HAMA (Human Anti-Mouse Antibodies)	800 µg/L	0.053 µmol/L
Hydralazine	1.44 mg/dL	0.073 mmol/L
Hydrocodone	0.0072 mg/dL	0.160 µmol/L
Ibuprofen	70.0 mg/dL	3.39 mmol/L
Leucovorin	15.0 mg/dL	0.293 mmol/L
Levothyroxine	0.0429 mg/dL	0.552 µmol/L
Loratadine	0.0087 mg/dL	0.227 µmol/L
Methotrexate	454 mg/dL	9.99 mmol/L
Metoclopramide	1.0 mg/dL	0.030 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
Olaparib	1.71 mg/dL	0.039 mmol/L
Omeprazole	0.840 mg/dL	0.024 mmol/L
Paclitaxel	1.0 mg/dL	0.012 mmol/L
Phenytoin	6.00 mg/dL	0.238 mmol/L
Salicylic acid	2.86 mg/dL	0.207 mmol/L
Theophylline	6.0 mg/dL	0.333 mmol/L
Topotecan	0.0019 mg/dL	0.045 µmol/L
Triglycerides, total	1500 mg/dL	16.9 mmol/L
Vancomycin hydrochloride	12.3 mg/dL	0.083 mmol/L
Vinblastine	0.0084 mg/dL	0.092 µmol/L
Vinorelbine	0.19 mg/dL	0.002 mmol/L

Other Limitations

- The results from this or any other diagnostic test should be used and interpreted only in the context of the overall clinical picture.
- Heterophilic antibodies in the serum or plasma of certain individuals may cause interference with immunoassays. These antibodies may be present in blood samples from individuals regularly exposed to animals or who have been treated with animal serum products. Results which are inconsistent with

clinical observations indicate the need for additional testing.

- Individuals receiving mouse immunoglobulin by parenteral routes may produce anti-mouse antibodies. Serum from such individuals may produce erroneous results.
- The VITROS CA 125 II has no high dose hook effect up to 340,000 U/mL.
- The VITROS CA 125 II test is not recommended as a screening procedure to detect cancer in the general population.
- Different test methods cannot be used interchangeably. OC 125 defined antigen in a given patient sample determined with different tests and from different manufacturers can vary due to differences in test methods and reagent specificity. A change to the test used during serial monitoring of a patient should be accompanied by additional sequential testing to confirm baseline concentrations. The results reported by the laboratory to the physician must include the identity of the CA 125 II test used.
- CA 125 test concentrations are elevated in 1-2% of healthy individuals and may be elevated in diseases other than ovarian carcinoma, including both benign and malignant disorders. CA 125 test concentrations greater than or equal to 35 U/mL may be found in patients with non-malignant conditions, such as pericarditis, cirrhosis, severe hepatic necrosis, endometriosis (Stages II-IV), first trimester pregnancy, and ovarian cysts or in patients with non-ovarian malignancies, such as uterine carcinoma, hepatoma, pancreatic adenocarcinoma, and lung cancer.
- A CA 125 test concentration below 35 U/mL does not indicate the absence of residual ovarian cancer because patients with histopathologic evidence of ovarian carcinoma may have CA 125 test concentrations within the range of healthy individuals. Clinical decisions should not be based on a VITROS CA 125 II test concentration below 35 U/mL.
- The test should not be performed until at least three weeks after the completion of primary chemotherapy and at least two months after abdominal surgery. This is recommended because it is not clear what effect, if any, these procedures may have on the CA 125 test concentration.
- For changes in tumor marker concentrations during therapy:
- Progressive disease is defined by an increase of at least 25%. Sampling should be repeated within two to four weeks for additional evidence.
- Partial remission is defined as a decrease of at least 50% in the tumor marker concentrations.
- Certain drugs are known to alter CA 125 concentrations in vivo. Please consult one of the published summaries for details.

Dilution

The dilution recovery and dilution imprecision product requirements were met for the VITROS Immunodiagnostic Products CA 125 II Reagent Pack. 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.

Expected Values

Adult Reference Interval
The adult reference interval was validated following CLSI document EP28-A3c *Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory; Approved Guideline* – Third Edition.

Unit (U/L)
≤35 U/mL

The number of test results from 60 healthy female and male blood donors that fell outside the current reference interval claim of >35 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 current limit, the reference interval claim of the current VITROS CA 125 II will be transferred to the updated VITROS CA 125 II Reagent Pack.

Table 1: Test results outside the current reference interval claim of VITROS CA 125 II Reagent Pack

System	Reagent Lot	Gender	No. of test results >35 U/mL
VITROS 5600	9991	Female	1
		Male	0

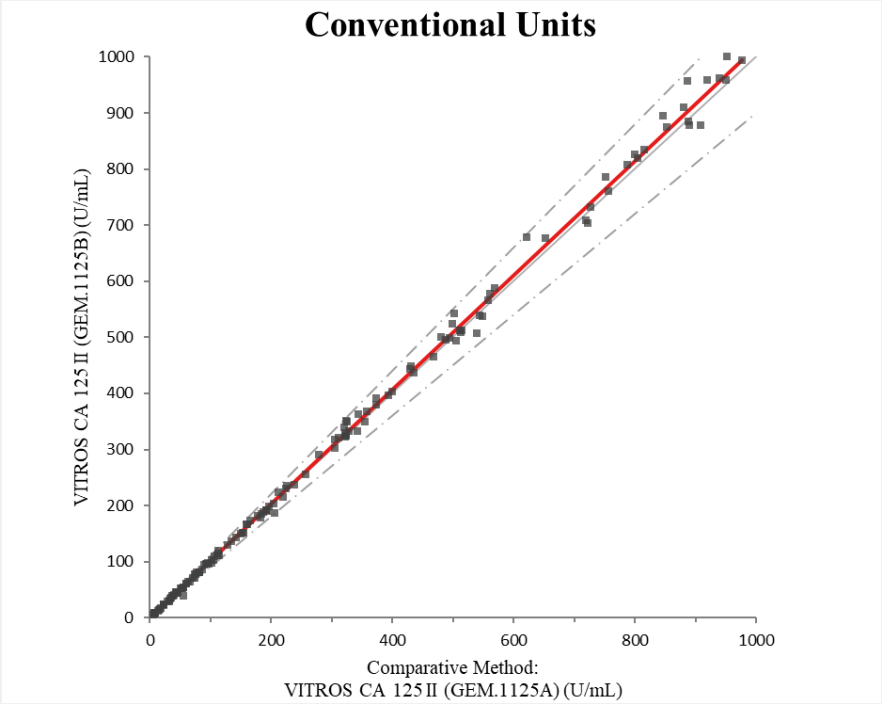
Traceability of Calibration

Calibration of the VITROS CA 125 II test 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 documents *Measurement Procedure Comparison and Bias Estimation Using Patient Samples. 3rd ed. CLSI guideline* EP09c; and *Evaluation of Total Analytical Error for Quantitative medical laboratory Measurement Procedures.* 2nd ed. CLSI guideline EP21.

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 125 reagent pack. The relationship between the 2 methods was determined by Passing Bablok regression.



VITROS System	n	Slope (95% CI)	Correlation Coefficient	Conventional Units (U/mL)	
				Range of Samples	Intercept (95% CI)
5600 vs. Comparative Method	146	1.018 (1.009 to 1.027)	0.999	5.74-1000	-0.449 (-1.444 to -0.166)

Conclusion

The conclusions drawn from the nonclinical tests (discussed above) demonstrate the VITROS Immunodiagnostic Products CA 125 II Reagent pack 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.