

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE**

A. 510(k) Number:

k042838

B. Purpose for Submission:

Notification of intent to manufacture and market the device: VITROS Chemistry Products Calibrator Kit 23, and VITROS Chemistry Products PALB Performance Verifier I and II

C. Measurand:

PreAlbumin (PALB) control and calibrator

D. Type of Test:

N/A

E. Applicant:

Ortho-Clinical Diagnostics, Inc

F. Proprietary and Established Names:

Proprietary - VITROS Chemistry Products Calibrator Kit 23 Established name - Prealbumin calibrator. Proprietary - VITROS Chemistry Products PALB Performance Verifier I and II Established name - Prealbumin quality control level 1 & 2.

G. Regulatory Information:

1. Regulation section: Calibrator 862.1150, Control 862.1660
2. Classification: Calibrator – Class II, Control – Class I
3. Product code: Calibrator - JIT, Control - JJX
4. Panel: 75 Chemistry

H. Intended Use:

1. Intended use(s): For *in vitro* diagnostic use only. VITROS Chemistry Products Calibrator Kit 23 is used to calibrate VITROS 5, 1 Chemistry Systems for the quantitative measurement of prealbumin.

For *in vitro* diagnostic use only. VITROS Chemistry Products PALB Performance Verifiers are assayed controls used to monitor the performance of PALB reagent on VITROS 5, 1 FS Chemistry Systems.

2. Indication(s) for use: For *in vitro* diagnostic use only. VITROS Chemistry Products Calibrator Kit 23 is used to calibrate VITROS 5, 1 Chemistry Systems for the quantitative measurement of prealbumin.

For *in vitro* diagnostic use only. VITROS Chemistry Products PALB Performance Verifiers are assayed controls used to monitor the performance of PALB reagent on VITROS 5, 1 FS Chemistry Systems.

3. Special conditions for use statement(s): For Prescription Use Only.

4. Special instrument requirements: Intended for the VITROS 5, 1 FS Chemistry Systems.

I. Device Description:

VITROS Chemistry Products Calibrator Kit 23 is a liquid ready to use kit containing five (5) levels for the calibration of VITROS 5, 1 Chemistry Systems for quantitative measurement of prealbumin. These calibrators are prepared from processed human serum to which inorganic salts, buffers and preservatives have been added. Testing at the individual donor level was non-reactive for Hepatitis B surface antigen (HBsAg), antibody to HCV, and antibody to HIV using FDA approved methods.

VITROS Chemistry Products PALB Performance Verifiers contain two levels of liquid ready to use assayed controls for use in monitoring performance of PALB reagents on VITROS 5, 1 Chemistry Systems. These controls are prepared from processed human serum to which inorganic salts, buffers and preservatives have been added. Testing at the individual donor level was non-reactive for Hepatitis B surface antigen (HBsAg), antibody to HCV, and antibody to HIV using FDA approved methods.

J. Substantial Equivalence Information:

1. Predicate device name(s): VITROS chemistry products calibrator kit 17 (hsCRP) and VITROS hsCRP Performance Verifiers.

2. Predicate 510(k) number(s): k041799
3. Comparison with predicate:

Calibrator		
Item	Device	Predicate
Intended use	For <i>in vitro</i> diagnostic use only. VITROS Chemistry Products Calibrator Kit 23 is used to calibrate VITROS 5, 1 Chemistry Systems for the quantitative measurement of prealbumin.	For <i>in vitro</i> diagnostic use only. VITROS Chemistry Products Calibrator Kit 17 is used in conjunction with VITROS Chemistry Products FS calibrator 1 to calibrate the VITROS 5, 1 Chemistry Systems for the quantitative measurement of C-Reactive Protein.
Fluid Matrix	A base matrix of human serum to which inorganic salts, buffers and preservatives have been added.	A base matrix of human serum to which inorganic salts, and preservatives have been added.
Analyte Levels	Five levels	Single level
Analyte	Prealbumin (transthyretin)	C-reactive Protein)
Traceability	CRM470	CRM470
Format	Liquid ready to use	Liquid ready to use

Controls		
Item	Device	Predicate
Intended use	For <i>in vitro</i> diagnostic use only. VITROS Chemistry Products PALB Performance Verifiers are assayed	For <i>in vitro</i> diagnostic use only. VITROS Chemistry Products hsCRP Performance Verifiers are assayed

Controls		
Item	Device	Predicate
	controls used to monitor the performance of PALB reagent on VITROS 5, 1 FS Chemistry Systems.	controls used to monitor the performance of hsCRP reagent on VITROS 5, 1 FS Chemistry Systems.
Fluid Matrix	A base matrix of processed human serum to which inorganic salts, buffers and preservatives have been added.	A base matrix of stabilized human serum to which analytes and preservatives have been added.
Analyte Levels	Low And High	Low And High
Analyte	Prealbumin (transthyretin)	hsCRP
Format	Liquid ready to use	Liquid ready to use

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

IRMM/IFCC (Institute for Reference Methods and Materials/ International Federation of Clinical Chemistry and Laboratory Medicine. CRM 470 (RPPHS – Reference Preparation for Proteins in Human Serum.)

L. Test Principle: N/A

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:* N/A

b. *Linearity/assay reportable range:* N/A

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

Traceability: VITROS Chemistry Products Calibrator Kit 23 is a liquid ready to use kit containing five (5) levels for the calibration of VITROS 5, 1 Chemistry Systems for quantitative measurement of prealbumin. These calibrators are prepared from processed human

serum to which inorganic salts, buffers and preservatives have been added. The values assigned to the VITROS Chemistry Products Calibrator kit 23 for prealbumin are traceable to the IRMM/IFCC (Institute for Reference Methods and Materials/ International Federation of Clinical Chemistry and Laboratory Medicine) and to CRM 470 (RPPHS – Reference Preparation for Proteins in Human Serum.)

VITROS Chemistry Products PALB Performance Verifiers contain two levels of liquid ready to use assayed controls for use in monitoring performance of PALB reagents on VITROS 5, 1 Chemistry Systems. These controls are prepared from processed human serum to which inorganic salts, buffers and preservatives have been added. Control Level I 10 mg/dL and Control Level II 26 mg/dL are the nominal values representative of the target control values used during the calibrator and control manufacturing process.

Stability:

The shelf life and opened-vial stability of the VITROS Chemistry Product Calibrator Kit 23 when stored at 2-8C is based on real time stability data and predetermined acceptance criteria.

The shelf life and reconstitution stability of the VITROS Chemistry Products PALB performance Verifiers I and II when stored at 2-8 C is based on real time stability data and predetermined acceptance criteria.

- d. *Detection limit:* N/A
- e. *Analytical specificity:* N/A
- f. *Assay cut-off:* N/A
- 2. Comparison studies:
 - a. *Method comparison with predicate device:* N/A
 - b. *Matrix comparison:* N/A
- 3. Clinical studies:
 - a. *Clinical Sensitivity:* N/A
 - b. *Clinical specificity:* N/A

c. Other clinical supportive data (when a. and b. are not applicable):
N/A

4. Clinical cut-off: N/A

5. Expected values/Reference range: N/A

N. Proposed Labeling:

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

O. Conclusion:

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