

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY**

A. 510(k) Number:

k060940

B. Purpose for Submission:

Addition of Haptoglobin to an existing device.

C. Measurand:

Alpha-1 Antitrypsin

Haptoglobin

D. Type of Test:

Quantitative immunoturbidimetric assay

E. Applicant:

Ortho-Clinical Diagnostics, Inc.

F. Proprietary and Established Names:

VITROS Chemistry Products Calibrator Kit 99

VITROS Chemistry Products AAT/HPT Performance Verifiers I, II, and III

G. Regulatory Information:

1. Regulation section:

21CFR§ 862.1660, Quality Control Material (Assayed and Unassayed)

21CFR§ 862.1150, Calibrator

2. Classification:

Calibrator - Class II

Quality control material - Class I

1. Product code:

JJX, Single (Specified) Analyte Controls (Assayed and Unassayed)

JIX, Calibrator, Multi-Analyte Mixture

4. Panel:

Chemistry (75)

H. Intended Use:

1. Intended use(s):

VITROS Chemistry Products Calibrator Kit 99 is used to calibrate VITROS 5, 1 FS Chemistry systems for the quantitative measurement of proteins in body fluids.

VITROS Chemistry Products AAT/HPT Performance Verifiers I, II, III are assayed controls used to monitor performance of protein measurements in body fluids with VITROS 5, 1 FS Chemistry systems.

2. Indication(s) for use:

Same as above

3. Special conditions for use statement(s):

For prescription use only.

4. Special instrument requirements:

For use in VITROS 5, 1 FS Chemistry systems (k031924).

I. Device Description:

The VITROS Chemistry Products Calibrator Kit 99 is a five level set of fluids used to calibrate VITROS 5, 1 FS Chemistry systems for the quantitative measurement of α 1-antitrypsin (AAT), and haptoglobin (HPT) using VITROS Chemistry Products AAT and HPT Reagents. VITROS Chemistry Products Calibrator 99 is prepared from processed human serum to which inorganic salts, buffers, and preservatives have been added.

The VITROS Chemistry Products AAT/HPT Performance Verifiers I, II, and III is a three level set of assayed liquid controls used to monitor the performance of α 1-antitrypsin (AAT), and haptoglobin (HPT) measurements, using VITROS Chemistry Products AAT and HPT Reagents with the VITROS 5, 1 FS Chemistry systems. The VITROS AAT/HPT Performance Verifiers are prepared from processed human serum to which inorganic salts, buffers, and preservatives have been added.

J. Substantial Equivalence Information:

1. Predicate device name(s):
 VITROS Chemistry Products Calibrator Kit 99
 VITROS Chemistry Products AAT Performance Verifiers I, II, and III
2. Predicate 510(k) number(s):
 K052819
3. Comparison with predicate:

Similarities		
Item	Device	Predicate
	VITROS Calibrator Kit 99 (New)	VITROS Calibrator Kit 99 (Current)
Standardization	BAM-IRMM-LGC (Institute for reference Methods and Materials/Laboratory of the Gov't Chemist) ERM-DA 470	Same
Sample type	Serum	Same
Number of levels	Five levels	Same
Matrix	Prepared from processed human serum to which salts, buffers and preservatives have been added	Same
Format	Liquid ready to use.	Same

Differences		
Item	Device	Predicate
Intended Use	VITROS Chemistry Products Calibrator Kit 99 is used to calibrate VITROS 5,	VITROS Chemistry Products Calibrator Kit 99 is used to calibrate

Differences		
Item	Device	Predicate
	1 FS Chemistry systems for the quantitative measurement of proteins in body fluids.	VITROS 5, 1 FS Chemistry systems for the quantitative measurement of α 1-antitrypsin (AAT).
Analytes	α 1-antitrypsin (AAT), and haptoglobin (HPT)	α 1-antitrypsin (AAT),

Similarities		
Item	Device	Predicate
	VITROS AAT/HPT Performance Verifiers I, II, III	VITROS AAT Performance Verifiers I, II, III
Standardization	BAM-IRMM-LGC (Institute for reference Methods and Materials/Laboratory of the Gov't Chemist) ERM-DA 470	Same
Sample type	Serum	Same
Number of levels	Three levels	Same
Matrix	Prepared from processed human serum to which salts, buffers and preservatives have been added	Same
Format	Liquid ready to use.	Same
Differences		
Intended Use	VITROS Chemistry Products Calibrator Kit 99 is used to calibrate VITROS 5, 1 FS Chemistry systems for the quantitative measurement of proteins in body fluids.	VITROS Chemistry Products Calibrator Kit 99 is used to calibrate VITROS 5, 1 FS Chemistry systems for the quantitative measurement of α 1-antitrypsin (AAT).
Analytes	α 1-antitrypsin (AAT), and haptoglobin (HPT)	α 1-antitrypsin (AAT),

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

None referenced.

L. Test Principle:

The VITROS Chemistry Products Calibrator Kit 99 (New) and VITROS Chemistry Products AAT/HPT Performance Verifiers I, II, III are to be used with VITROS 5, 1 FS Chemistry systems (k031924). The VITROS 5, 1 FS Chemistry systems is a random access, fully automated clinical chemistry analyzer, intended for use in the in vitro quantitative measurement of a variety

of analytes in certain biological fluids. The analyzer operates in conjunction with reagents, calibrators and controls designed for use with the system.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

Not applicable.

The new device is for the addition of the haptoglobin analyte to Calibrator Kit 99 and Performance Verifiers I, II, III. Haptoglobin immunological test system (§866.5460) is a Class II exempt from premarket notification procedures. Refer to predicate device (k052819) for precision/reproducibility studies of AAT.

b. *Linearity/assay reportable range:*

Not applicable.

The new device is for the addition of the haptoglobin analyte to Calibrator Kit 99 and Performance Verifiers I, II, III. Haptoglobin immunological test system (§866.5460) is a Class II exempt from premarket notification procedures. Refer to predicate device (k052819) for linearity studies of AAT.

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

The values assigned to the VITROS Chemistry Products Calibrator Kit 99 for AAT/HPT are traceable to BAM-IRMM-LGC (Bundesanstalt für Materialforschung und-prüfung/Institute for Reference Methods and Materials/Laboratory of the Gov't Chemist) ERM-DA 470 Reference Material. A five level set of calibrators are prepared through VITROS 5, 1 FS Chemistry System on-analyzer dilution of ERM-DA470 and are used to calibrate the Manufacturer's Selected Measurement Procedure, a VITROS 5, 1 FS Chemistry System analyzer using VITROS Chemistry Products AAT or HPT Reagents, respectively. The calibration standards and the VITROS chemistry System are used to support value assignment for working calibrators, VITROS Chemistry Products Calibrator Kit 99 (Master Lot).

The Master Lot and the Manufacturer's Selected Measurement Procedure, a VITROS 5, 1 FS Chemistry System analyzer using VITROS Chemistry Products AAT or HPT Reagents, respectively transfers the trueness of the working calibrators to new product lots of the VITROS Chemistry Products AAT/HPT Reagent and VITROS Chemistry Products Calibrator Kit 99.

Calibrator Kit Stability – Unopened kit are stable until expiration date printed on the label when stored refrigerated at 2°-8°C. Opened vials are stable at ≤3 days when stored capped between 2°-8°C.

Performance Verifiers Stability – Unopened kit are stable until expiration date printed on the label when stored refrigerated at 2°-8°C. The stability of opened vials stored capped between 2°-8°C is up to 4 weeks.

d. *Detection limit:*

Not applicable

The new device is for the addition of the haptoglobin analyte to Calibrator Kit 99 and Performance Verifiers I, II, III. Haptoglobin immunological test system (§866.5460) is a Class II exempt from premarket notification procedures. Refer to predicate device (k052819) for determination of detection limit.

e. *Analytical specificity:*

Not applicable.

The new device is for the addition of the haptoglobin analyte to Calibrator Kit 99 and Performance Verifiers I, II, III. Haptoglobin immunological test system (§866.5460) is a Class II exempt from premarket notification procedures. Refer to predicate device (k052819) for analytical specificity studies.

2. Comparison studies:

a. *Method comparison with predicate device:*

Not applicable.

The new device is for the addition of the haptoglobin analyte to Calibrator Kit 99 and Performance Verifiers I, II, III. Haptoglobin immunological test system (§866.5460) is a Class II exempt from premarket notification procedures. Refer to predicate device (k052819) for method comparison with predicate device.

b. *Matrix comparison:*

Not applicable

3. Clinical studies:

a. *Clinical Sensitivity:*

Not applicable

b. *Clinical specificity:*

Not applicable

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

Not applicable

4. Clinical cut-off:

Not applicable

5. Expected values/Reference range:

Not applicable

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.