

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

**A. 510(k) Number:**

k103701

**B. Purpose for Submission:**

Modification of existing calibration material

**C. Measurand:**

Protein analytes: Alpha-Acid-Glycoprotein (AAG), Alpha-1-Antitrypsin (AAT), Anti-streptolysin-O, Complement C3, Complement C4, Haptoglobin, Immunoglobulin A, Immunoglobulin G, Immunoglobulin M, Prealbumin, Rheumatoid Factor, Transferrin

**D. Type of Test:**

Calibrator

**E. Applicant:**

Siemens Healthcare Diagnostics, Inc.

**F. Proprietary and Established Names:**

ADVIA Chemistry Liquid Specific Protein Calibrator

**G. Regulatory Information:**

1. Regulation section:  
21 CFR § 862.1150 - Calibrator
2. Classification:  
Class II
3. Product code:  
JIX, Calibrator, Multi-Analyte Mixture
4. Panel:  
Immunology (82)

**H. Intended Use:**

1. Intended use(s):  
See indications for use, below.
2. Indication(s) for use:  
The ADVIA Chemistry Liquid Protein Calibrator is for in vitro diagnostic use in the calibration of ADVIA® Chemistry systems for the Alpha-Acid-Glycoprotein (AAG), Alpha-1-Antitrypsin (AAT), Anti-streptolysin-O<sub>2</sub> (ASO<sub>2</sub>), Complement C3 (C3), Complement C4 (C4), Haptoglobin (HAPT), Immunoglobulin A<sub>2</sub> (IGA<sub>2</sub>), Immunoglobulin G<sub>2</sub> (IGG<sub>2</sub>), Immunoglobulin M<sub>2</sub> (IGM<sub>2</sub>), Prealbumin (PREALB), Rheumatoid Factor (RF), Transferrin (TRF) methods
3. Special conditions for use statement(s):  
For prescription use
4. Special instrument requirements:  
ADVIA® Chemistry systems 1650, 1800, 2400, and 1200

**I. Device Description:**

ADVIA Chemistry Liquid Specific Protein Calibrator is a multi-analyte, liquid, buffer based product containing multiple analytes derived from human source. The kit consists of 1 vial each of 6 calibrator levels (6 vials total in the package) which are

ready for use (no preparation is required). The volume per vial is 1.0 mL. The low level (level 1) is a zero-level calibrator with no analytes present in the formulation. The target concentrations of Levels 2 – 6 are: 40, 80, 150, 300, and 640 mg/dL.

**J. Substantial Equivalence Information:**

1. Predicate device name(s):  
Randox Liquid Protein Calibrators
2. Predicate K number(s):  
k031608 (IgA, IgG, IgM, ASO, Prealbumin, C3, C4)  
k061056 (Haptoglobin, IgA, IgG, IgM, Transferrin, C3, C4)
3. Comparison with predicate:

<b>Similarities</b>		
Item	Device	Predicates
Intended Use	for <i>in vitro</i> diagnostic use in the calibration of ADVIA® Chemistry system for the <b>Alpha-Acid-Glycoprotein (AAG)</b> , Alpha-1-Antitrypsin (AAT), Anti-streptolysin-O_2 (ASO_2), Complement C3 (C3), Complement C4 (C4), Haptoglobin (HAPT), Immunoglobulin A_2 (IGA_2), Immunoglobulin G_2 (IGG_2), Immunoglobulin M_2 (IGM_2), Prealbumin (PREALB), Rheumatoid Factor (RF), Transferrin (TRF) methods	<p><b>k031608:</b> For the calibration of ASO, Complement C3, Complement C4, CRP, Ferritin, IgA, IgG, IgM, Prealbumin and Transferrin assays (all neat sample assays). These calibrators also contain a-1-Antitrypsin (AAT) and Rheumatoid Factor (RF) for use in the calibration of AAT and RF assays on the Bayer Advia 1650 analyzer only. For the calibration of a-1-antitrypsin, a-1-acid glycoprotein, IgA, IgG, IgM and Transferrin assays which require sample pre-dilution.</p> <p><b>k061056:</b> for in vitro diagnostic use in the calibration of ASO, Complement C3, Complement C4, CRP, Ferritin, Haptoglobin, IgA, IgG, IgM, Prealbumin, and Transferrin assays on Clinical Chemistry and Immunoassay systems</p>
Analytes Present	Anti-streptolysin-O, Alpha-1-Antitrypsin, Prealbumin, Rheumatoid Factor, Immunoglobulin A	Same

<b>Similarities</b>		
<b>Item</b>	<b>Device</b>	<b>Predicates</b>
	Immunoglobulin G, Immunoglobulin M, Complement C3, Complement C4, Haptoglobin, Transferrin, Ferritin, Alpha-acid-glycoprotein, CRP	
Format	Liquid buffered base (1.0 ml vials)	Same
Levels	6 (lowest level is a zero-level without analytes present)	Same
Stability	24 months unopened 28 days opened	Same

<b>Differences</b>		
<b>Item</b>	<b>Device</b>	<b>Predicates</b>
Value assigned analytes	Anti-streptolysin-O, Alpha-1-Antitrypsin, Prealbumin, Rheumatoid Factor, Immunoglobulin A Immunoglobulin G, Immunoglobulin M, Complement C3, Complement C4, Haptoglobin, Transferrin, Alpha-acid-glycoprotein	ASO AAT Prealbumin RF IgA IgG IgM Complement C3 Complement C4 Haptoglobin Transferrin Alpha-acid-glycoprotein Ferritin CRP
Instrument Systems Supported	ADVIA® Chemistry Systems (1200, 1650, 1800, 2400)	Abbott Spectrum, Abbott Aeroset, Abbott Architect i2000, Architect i 2000sr, Ace analyser, Bayer Advia 1650, Advia 2400, Advia 1200, Dade Dimension RXL, Dimension AR, Hitachi 704, Hitachi 717, Hitachi 911, Hitachi 917, Hitachi 912, Hitachi 747, Kone progress, AU800, AU600, AU400, AU2700, AU5400, Selectra Vitalab, Synchron CX4, Synchron CX5, Synchron CX7, Synchron LX20, ILAB300, ILAB900, ILAB1800, ILAB600, RX Daytona, RX Imola, Cobas Mira, Cobas Mira S, Cobas Mira Plus

There are no changes to the existing products except the addition of AAG value assignment process and the addition of the AAG analyte to the intended use of the device. The product has the same formulation, part number, manufacturing, packaging, and labeling as the current ADVIA Chemistry Liquid Specific Protein Calibrator. All of the analytes in k031608 and k061056 are present but may not have a value assignment (Ferritin and CRP) in this iteration of the ADVIA Chemistry Liquid Specific Protein Calibrators.

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

Guidance for Industry - Abbreviated 510(k) Submissions for In Vitro Diagnostic Calibrators; Final

**L. Test Principle:**

Not applicable

**M. Performance Characteristics (if/when applicable):**

1. Analytical performance:

a. *Precision/Reproducibility:*

Not applicable for this device type.

b. *Linearity/assay reportable range:*

Not applicable.

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

Traceability:

The Alpha-Acid Glycoprotein (AAG) analyte in ADVIA Chemistry systems Liquid Specific Protein calibrator is traceable to the International Reference Material for Serum Proteins, serum-based lyophilized ERMDA-470 (previously known as CRM470).

Value Assignment:

Assigned lot-specific values will be utilized for the AAG calibration (and other analytes) on ADVIA Chemistry systems. The lot-specific calibrator values are generated via value assignment on the ADVIA 1650 Chemistry system using Master Lot calibrators. These values are also used on the other ADVIA Chemistry platforms (1650, 1800, 1200, and 2400).

Stability:

Unopened vials stored as directed in the package insert (2 – 8 °C) were shown to be stable for 24 months in a real-time stability experiment. Opened vials were shown to be stable for 28 days when stored at as directed in the package insert (2 – 8 °C). The acceptance criterion for each method is expressed in terms of a drift in recovery versus time. Each analyte must meet the pre-determined acceptance criteria for storage conditions recommended by the manufacturer.

d. *Detection limit:*

Not applicable.

e. *Analytical specificity:*

Not applicable.

f. *Assay cut-off:*

Not applicable.

2. Comparison studies:
  - a. *Method comparison with predicate device:*  
Not applicable
  - b. *Matrix comparison:*  
Not applicable
3. Clinical studies:
  - a. *Clinical Sensitivity:*  
Not applicable
  - b. *Clinical specificity:*  
Not applicable
4. Clinical cut-off:  
Not applicable.
5. Expected values/Reference range:  
The assigned values are provided in the labeling.

**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 substantial equivalence decision.