

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

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

k103548

**B. Purpose for Submission:**

New Device

**C. Measurand:**

Calibration materials for total IgE assay

**D. Type of Test:**

Not applicable

**E. Applicant:**

Siemens Healthcare Diagnostics, Inc.

**F. Proprietary and Established Names:**

ADVIA Centaur® Calibrator 80

**G. Regulatory Information:**

1. Regulation section:  
21 CFR §862.1150, Calibrator
2. Classification:  
Class II
3. Product code:  
JIT – Calibrator, Secondary
4. Panel:  
Clinical Chemistry (75)

**H. Intended Use:**

1. Intended use(s):  
For *in vitro* diagnostic use in calibrating the ADVIA Centaur® Total IgE (tIgE) quantitative assay on the ADVIA Centaur system.
2. Indication(s) for use:  
Same as Intended Use.
3. Special conditions for use statement(s):  
For Prescription Use Only.
4. Special instrument requirements:  
ADVIA Centaur

**I. Device Description:**

The ADVIA Centaur® Calibrator 80 is a 2 level human IgE in equine serum containing detergents and preservatives. Two vials of the lyophilized low calibrator and two levels of lyophilized high calibrator are included. All human source materials used in the manufacture of this product was tested by FDA-approved methods and found nonreactive for hepatitis B surface antigen (HBsAg), antibody to hepatitis C (HCV), and antibody to HIV-1/2. The Calibrators 80 target and acceptance ranges are summarized in the table below:

Analyte	Level	Calibrator Target (IU/mL)	Acceptance Range (IU/mL)
tIgE	Level 1 (Low)	35	28.5 - 39.9
	Level 2 (High)	1825	1425 - 2205

Each Calibrator Kit includes a Calibrator Assigned Value Card that provides the calibrator values for each analyte in the low and high calibrators. Customers can use the barcode scanner or the keyboard to enter the calibrator values on to the ADVIA Centaur analyzer.

**J. Substantial Equivalence Information:**

- Predicate device name(s):  
Siemens Healthcare Diagnostics (formerly Ciba Corning Diagnostics Corp.) ACS Calibrator B
- Predicate 510(k) number(s):  
k920372
- Comparison with predicate:

Similarities		
Item	ADVIA Centaur® Calibrator 80 (New Device)	ADVIA Centaur® Calibrator B (Predicate Device)
Intended Use	For <i>in vitro</i> diagnostic use in calibrating the ADVIA Centaur® Total IgE (tIgE) assay on the ADVIA Centaur system.	For <i>in vitro</i> diagnostic use in calibrating the following assays using ADVIA Centaur® or ACIS:180® Systems: Digoxin; FSH; Total IgE; LH, LH2, Prolactin; Total hCG; TSH.
Number of Levels	2	Same
Form	Lyophilized	Same
Matrix	Equine serum	Same
Total IgE Target Concentrations	Low Calibrator = 35 IU/mL High Calibrator = 1825 IU/mL	Same
Storage Temperature	2 - 8°C	Same
Special instruments	ADVIA Centaur	ADVIA Centaur® or ACIS:180® Systems
Differences		
Item	ADVIA Centaur® Calibrator 80 (New Device)	ADVIA Centaur® Calibrator B (Predicate Device)
Analytes	Single Analyte: Total IgE (tIgE)	Multi Analyte: Digoxin, FSH, Total IgE, LH LH2, Prolactin, Total hCG, TSH

Ingredients	After reconstitution, low or high levels of human IgE in equine serum, detergents and preservatives	After reconstitution, low or high levels of the analytes listed in <i>Intended Use</i> in equine serum with preservatives and protein stabilizers
Stability	Unopened – until expiration date on the vial label Reconstituted - 60 days On-board - 8 hours	Unopened – until expiration date on the vial label Reconstituted - 28 days On-board - 4 hours
Fill Volume	2 mL/vial	5 mL/vial

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

None were referenced.

**L. Test Principle:**

Not applicable

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

1. Analytical performance:

a. *Precision/Reproducibility:*

Not applicable.

b. *Linearity/assay reportable range:*

Not applicable.

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

Traceability:

ADVIA Centaur Calibrator 80 is traceable to the WHO international standard 75/502. The values for Calibrator 80 are read off the set of internal standards which is comprised of seven levels and span the range of the assay. These internal Total IgE standards are traceable to WHO material 75/502.

Value Assignment:

Values are assigned using a set of seven internal standards. Calibrator values are assigned to these internal standards and are verified with the WHO international standard 75/502.

Value Assignment of ADVIA Centaur Calibrator 80 is performed using one ADVIA Centaur Total IgE reagent lot, 20 replicates, and a set of internal standards on one ADVIA Centaur analyzer according to Siemens Value Assignment Procedure. This testing is done in a single day with one operator.

The tIgE assay utilizes a 2-Point calibration system. Calibrator values are assigned using master curve standards which span the entire range of the assay. Two sets of controls are run to verify the validity of the runs. In order to verify that values are correct, the calibrators are substituted for Master Curve standards and known controls are calculated off the newly assigned calibrators. Control values are then compared to specifications to ensure that the values of the new 2-Point calibrators are correctly assigned. The Total IgE Calibrators have expected values of 35 and 1825 IU/mL.

Stability:

Real Time, accelerated, open vial) and on board stability studies were carried out on the ADVIA Centaur. Stability testing protocols and acceptance criteria were described and found to be adequate.

*Open vial stability:*

The open-vial (reconstituted) claim is 60 days at 2-8°C.

*On Board Stability:*

The On-System stability claim is onboard 8-hour at room temperature.

*Real time/Closed Vial stability:*

The Shelf-life stability is 16 months refrigerated (2-8°C); however it will be updated as additional real time stability data becomes available. Product label will state “Lyophilized–until the expiration date on the vial label”.

Dilution study:

Not applicable.

*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

*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.