

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

A. 510(k) Number:

k083159

B. Purpose for Submission:

Clearance of new device

C. Measurand:

Low molecular weight heparin

D. Type of Test:

Control/Calibrator

E. Applicant:

SIEMENS HEALTHCARE DIAGNOSTICS

F. Proprietary and Established Names:

Berichrom Heparin LMW Calibrator

Berichrom Heparin LMW Control 1

Berichrom Heparin LMW Control 2

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
JPA	II	21 CFR 864.5425	81 HEMATOLOGY
GIZ	II	21 CFR 864.5425	81 HEMATOLOGY
GGC	II	21 CFR 864.5425	81 HEMATOLOGY

H. Intended Use:

1. Intended use(s):

Berichrom Heparin LMW Calibrator is an *in vitro* diagnostic product used for the calibration of the Berichrom Heparin assay for measurement of low molecular weight (LMW) heparin.

Berichrom Heparin LMW Control 1 is an assayed, low level, quality control material for assessment of precision and analytical bias in the quantitative determination of low molecular weight (LMW) heparin with the Berichrom Heparin assay.

Berichrom Heparin LMW Control 2 is an assayed, high level, quality control material for assessment of precision and analytical bias in the quantitative determination of low molecular weight (LMW) heparin with the Berichrom Heparin assay.

2. Indication(s) for use:

3. Special conditions for use statement(s):

4. Special instrument requirements:

I. Device Description:

Berichrom Heparin LMW Calibrator

Berichrom Heparin LMW Calibrator is a lyophilized product containing low molecular weight (LMW) heparin from porcine intestine and buffered human plasma. Each package contains 6 vials; each vial requires reconstitution with 1.0 mL distilled or deionized water.

Berichrom Heparin LMW Control 1

Berichrom Heparin LMW Control 1 is a lyophilized, low level, assayed control containing low molecular weight (LMW) heparin from porcine intestine and buffered human plasma. Each package contains 6 vials; each vial requires reconstitution with 1.0 mL distilled or deionized water.

Berichrom Heparin LMW Control 2

Berichrom Heparin LMW Control 2 is a lyophilized, high level, assayed control containing low molecular weight (LMW) heparin from porcine intestine and buffered human plasma. Each package contains 6 vials; each vial requires reconstitution with 1.0 mL distilled or deionized water.

J. Substantial Equivalence Information:

Predicate	Item	Similarities	Differences
Berichrom Heparin LMW Calibrator			
Calibration Plasma LMW Heparin – K030964	Intended Use	For the calibration of low molecular weight heparin	For the calibration of the Berichrom Heparin assay, predicate can be used to calibrate chromogenic assays
	Form	Lyophilized	
	Matrix	Plasma	
	Traceability	WHO Standard	
	Levels		One, predicate 3 levels
Berichrom Heparin LMW Control 1/2			
Control Plasma LMW Heparin – K030965	Intended Use	Assayed control for the measurement of low molecular control	
	Form	Lyophilized	
	Analyte	Low molecular weight	
	Matrix	Plasma	
	Levels		1 of each Control, sold separately, predicate 2 levels sold as a kit

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

STANDARDS			
Title and Reference Number			

Other Standards

GUIDANCE			
Document Title	Office	Division	Web Page
Guidance for	OIVD		http://www.fda.gov/cdrh/mdufma/guidance/1215.html

Industry and FDA Staff: Bundling Multiple Devices or Multiple Indications in a Single Submission	
Guidance for Industry and FDA Staff - Assayed and Unassayed Quality Control Material	OIVD http://www.fda.gov/cdrh/oivd/guidance/2231.html

L. Test Principle:

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):*

The assigned values for Berichrom Heparin LMW Calibrator, Berichrom Heparin LMW Control 1 and Berichrom Heparin LMW Control 2 are traceable to the 2nd World Health Organization (WHO) International Standard for low molecular weight heparin. Assigned values are obtained from multiple determinations, on multiple coagulation instruments and Berichrom Heparin lots. A typical assigned value for the calibrator is 1.40 IU/mL. Typical control values are 0.40 IU/mL for Control 1 and 0.90 IU/mL for Control 2.

Stability Testing

Shelf life (Closed)

Study Duration

24 month shelf life; studies performed for 1 month past labeled shelf life.

Testing Frequency

Day 0; 6, 9, 12, 18, 19, 24 and 25 months

Storage

+2 to +8°C

Replicates

Calibrator: Three six-point calibration curves are generated from three vials of calibrator; a mean calibration curve is established from the three curves. At each time point, a vial is tested in duplicate.

Controls: At each time point, a vial is tested in duplicate.

Acceptance Criteria

Calibrator & Controls: Results obtained must not deviate more than $\pm 20\%$ compared to Day 0 results.

The mean value at each time point is compared to the Day 0 is value. Results obtained must meet the acceptance criteria. Shelf-life (expiration) dating assignment at commercialization reflects the real-time data on file at Siemens Healthcare Diagnostics Inc.

Reconstituted (Open)

Study Duration

24 month shelf life; studies performed for 1 month past labeled shelf life

Testing Frequency

Day 0; 6, 9, 12, 18, 19, 24 and 25 months

Storage

+15 to +25°C; tested after reconstitution at various time points up to 25 hours

+2 to +8°C; tested after reconstitution at various time points up to 49 hours

≤-18°C; tested after reconstitution at various time points up to 5 weeks

Replicates

Calibrator: Three six-point calibration curves are generated from three vials of calibrator; a mean calibration curve is established from the three curves. At each time point, a vial is tested in duplicate.

Controls: At each time point, a vial is tested in duplicate.

Acceptance Criteria

Results obtained must not deviate more than $\pm 20\%$ compared to the freshly reconstituted vial results.

The mean value at each time point is compared to the value obtained from a freshly reconstituted vial. Results obtained must meet the 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:

Values are determined using six reference curves derived on six coagulometer instruments with two different reagent lots. 1 run on each reference curve, 4 vials, and 2 replicates per vial tested for a total of 48 values. The assigned value is the mean of the 48 values.

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.

