

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

A. 510(k) Number:

k083175

B. Purpose for Submission:

Bundled submission for the clearance of new devices

C. Measurand:

Low molecular weight heparin

D. Type of Test:

Control/Calibrator

E. Applicant:

SIEMENS HEALTHCARE DIAGNOSTICS

F. Proprietary and Established Names:

Berichrom Heparin UF Calibrator

Berichrom Heparin UF Control 1

Berichrom Heparin UF 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 UF Calibrator

For the calibration of the Berichrom Heparin assay for measurement of unfractionated (UF) heparin.

Berichrom Heparin UF Control 1

For use as a low level assayed control for the quantitative measurement of unfractionated (UF) heparin with the Berichrom Heparin assay.

Berichrom Heparin UF Control 2

For use as a high level assayed control for the quantitative measurement of unfractionated (UF) 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 UF Calibrator

Berichrom Heparin UF Calibrator is a lyophilized product containing unfractionated (UF) 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 UF Control 1

Berichrom Heparin UF Control 1 is a lyophilized, low level, assayed control containing unfractionated (UF) 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 UF Control 2

Berichrom Heparin UF Control 2 is a lyophilized, high level, assayed control containing unfractionated (UF) 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 UF Calibrator			
Dade Behring Calibrator and Controls–K042941	Intended Use	For the calibration of heparin assay	
	Form	Lyophilized	
	Matrix	Plasma	
	Traceability	WHO Standard	
	Levels	One level	
Berichrom Heparin UF Control 1/2			
Dade Behring Calibrator and Controls K042941	Intended Use	Assayed control for the measurement of low molecular control	
	Form	Lyophilized	
	Analyte	Low molecular weight	
	Matrix	Plasma	
	Levels	Low and high control	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 Industry and FDA Staff: Bundling Multiple Devices or Multiple Indications in a Single Submission	OIVD		http://www.fda.gov/cdrh/mdufma/guidance/1215.html
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 UF Calibrator, Berichrom Heparin UF Control 1 and Berichrom Heparin UF Control 2 are traceable to the 5th World Health Organization (WHO) International Standard for unfractionated heparin. Assigned values are obtained from multiple determinations, on multiple coagulation instruments and Berichrom Heparin

lots. A typical assigned value for the calibrator is 1.20 IU/mL. Typical control values are 0.20 IU/mL for Control 1 and 0.60 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 calibrator 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

Control 1: Results obtained must not deviate more than ± 0.05 IU/mL compared to Day 0 results

Calibrator & Control 2: 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 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

Control 1: Results obtained must not deviate more than ± 0.05 IU/mL compared to the freshly reconstituted vial results.

Calibrator & Control 2: Results 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.

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

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+2 to +8°C

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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 multiple reagent lots. 4 vials of control, 2 replicates per vial tested on each curve 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.

