

**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
<b>Berichrom Heparin UF Calibrator</b>			
<b>Dade Behring Calibrator and Controls–K042941</b>	<b>Intended Use</b>	<b>For the calibration of heparin assay</b>	
	<b>Form</b>	<b>Lyophilized</b>	
	<b>Matrix</b>	<b>Plasma</b>	
	<b>Traceability</b>	<b>WHO Standard</b>	
	<b>Levels</b>	<b>One level</b>	
<b>Berichrom Heparin UF Control 1/2</b>			
<b>Dade Behring Calibrator and Controls K042941</b>	<b>Intended Use</b>	<b>Assayed control for the measurement of low molecular control</b>	
	<b>Form</b>	<b>Lyophilized</b>	
	<b>Analyte</b>	<b>Low molecular weight</b>	
	<b>Matrix</b>	<b>Plasma</b>	
	<b>Levels</b>	<b>Low and high control</b>	<b>1 of each Control, sold separately, predicate 2 levels sold as a kit</b>

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

<b>STANDARDS</b>
<b>Title and Reference Number</b>

<b>Other Standards</b>
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GUIDANCE			
Document Title	Office	Division	Web Page
Guidance for Industry and FDA Staff: Bundling Multiple Devices or Multiple Indications in a Single Submission	OIVD		<a href="http://www.fda.gov/cdrh/mdufma/guidance/1215.html">http://www.fda.gov/cdrh/mdufma/guidance/1215.html</a>
Guidance for Industry and FDA Staff - Assayed and Unassayed Quality Control Material	OIVD		<a href="http://www.fda.gov/cdrh/oivd/guidance/2231.html">http://www.fda.gov/cdrh/oivd/guidance/2231.html</a>

**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  $\pm 0.05$  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  $\pm 0.05$  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.

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#### 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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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.

