

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE**

A. 510(k) Number:

k070144

B. Purpose for Submission:

New Device

C. Measurand:

Calibrator and control materials for Inhibin A

D. Type of Test:

Not applicable.

E. Applicant:

Beckman Coulter Inc.

F. Proprietary and Established Names:

Access Inhibin A Calibrators and QC

G. Regulatory Information:

1. Regulation section:

21 CFR § 862.1150

21 CFR § 862.1660

2. Classification:

Class II

Class I (reserved)

3. Product code:

JIS, calibrator secondary

JJX, single (specified) analyte controls (assayed and unassayed)

4. Panel:

Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):

The Access Inhibin A calibrators are intended to calibrate the Access Inhibin A assay for the quantitative determination of dimeric Inhibin A levels in human serum and plasma using the Access Immunoassay Systems.

The Access Inhibin A QC is intended for monitoring system performance of the Access Inhibin A assay.

2. Indication(s) for use:

See Intended use (above).

3. Special conditions for use statement(s):

For professional use.

3. Special instrument requirements:

Access Inhibin A Calibrators and QC is used to assess the performance of the Access Inhibin A Immunoassay System.

I. Device Description:

The Access Inhibin A Calibrators and Controls are designed for use with the Access Inhibin A Reagent for the generation of and control of the Inhibin A calibration curve on Beckman Coulter's Access Immunoassay Systems. The Access Inhibin A Calibrator Kit contains 7 x 2.5 mL bottles, one for each of seven calibrator levels. The Access Inhibin A Control Kit contains 3 X 2.5 mL bottles, one for each level of three control levels. The Access Immunoassay Systems utilize a competitive binding immunoenzymatic method for quantitative analyte measurement.

J. Substantial Equivalence Information:

1. Predicate device name(s):
DSL Inhibin A Calibrators and Controls
2. Predicate 510(k) number(s):
k002128
3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Analyte	Inhibin A	Inhibin A
Calibrator Standardization	WHO 91/624	WHO 91/624

Differences		
Item	Device	Predicate
Matrix	Bovine Serum Albumen	Fetal Bovine Serum
Calibrator Range	0-1500 pg/mL	0-1000 pg/mL
Quality Control Material	3 provided	2 provided
Assay Type	automated immunoassay	manual ELISA

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

None identified.

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):*

The inhibin A used in the controls and calibrators are traceable to WHO 91/624. Exact concentrations of the calibrators will be listed in the labeling for each lot. Expected results of the controls will be accompanied by the mean and SD for each lot in the labeling.

Stability characteristics of the Access controls and calibrators were determined using real time studies to determine estimated storage stability at 2 – 30 °C. Open vial stability of the controls was determined and supported a claim of 28 days at 2-30 °C. Open vial stability of the calibrators was determined and supported a claim of 28 days at 2-30 °C. Shelf life stability for both calibrators and controls is claimed to be 34 days based on on-going real time studies. The shelf life listed in the labeling will reflect the time of the real time data tested up to that point.

- 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:

The expected values are provided in the labeling for each lot.

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.