

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

A. 510(k) Number:

K060133

B. Purpose for Submission:

Premarket Notification 510(k) of intention to manufacture and market the Ischemia Albumin Cobalt Binding Test (ACB® Test) Assay Verification Set

C. Measurands:

Quality Control Material (assayed) for Albumin Cobalt Binding (ACB)

D. Type of Test:

Not Applicable

E. Applicant:

Inverness Medical Innovations, Inc.

F. Proprietary and Established Names:

Albumin Cobalt Binding (ACB) Test Assay Verification Set

G. Regulatory Information:

1. Regulation section:

21 CFR §862.1660; Single (Specified) Analyte Controls (assayed and unassayed)

2. Classification:

Class I

3. Product code:

JJX; Single (Specified) Analyte Controls (assayed and unassayed)

4. Panel:

Chemistry (75)

H. Intended Use:

1. Intended use(s):

The Ischemia Albumin Cobalt Binding Test (ACB®) Assay Verification Set is intended for use in verifying accuracy of the ACB Test on the Roche Integra 700/800. It is recommended as a part of assay installation.

2. Indication(s) for use:

The Ischemia Albumin Cobalt Binding Test (ACB®) Assay Verification Set is intended for use in verifying accuracy of the ACB Test on the Roche Integra 700/800. It is recommended as a part of assay installation.

3. Special condition for use statement(s):

Not Applicable

4. Special instrument Requirements:

Roche Integra 700/800

I. Device Description:

The ACB® Test Assay Verification Set (AVS) is an assayed control material with established albumin cobalt binding capacity. It is a single use, non-sterile, in vitro diagnostic device consisting of twenty (20) single vial 0.5mL aliquots of serum based samples. The samples are assigned IMA values over the physiological range (40-180U/mL) and at points just above and just below the 85U/mL cut-off. Sample value range is such that an analytical correlation study can be evaluated by the user to determine whether their analyzer is accurately measuring IMA levels in clinical specimens. The AVS device is supplied in frozen liquid form and is stable up to the expiry date.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Maine Standards Company VALIDATE CHEM 3 Calibration Verification Test Set.

2. Predicate k number(s):

K012119

3. Comparison with predicate:

Comparison of Ischemia Albumin Cobalt Binding Test (ACB®) Assay Verification Set k060133 to the Predicate Maine Standards Company VALIDATE CHEM 3 Calibration Verification Test Set k012119

Characteristics	Albumin Cobalt Binding Test (ACB®) Assay Verification Set k060133	Maine Standards Company VALIDATE CHEM 3 Calibration Verification Test Set k012119
Intended Use	For use in verifying accuracy of the ACB Test on the Roche Integra 700/800. It is recommended as part of assay installation. For in vitro diagnostic use.	For in vitro diagnostic use in quantitatively verifying calibration, validating reportable ranges and determining linearity in automated, semi-automated and manual chemistry systems.
Matrix	EDTA and CoCl ₂ in off-clot human serum	Human serum protein base
Form	Frozen liquid	Liquid ready to use
Levels	20 levels covering the physiological range	6 including zero
Analytes	Single analyte representative of ischemia modified albumin	Multiple analytes of total protein, albumin, and cholesterol.
Analyzer	Roche Integra 700/800	Automated, semi-automated and manual chemistry systems, including Roche Integra Systems
Vial Volume	0.5mL per vial	5.0mL of each level
Storage and Stability Unopened	Until expiry when frozen at -70°C or 4 weeks when frozen at -20°C	Until expiration at 2-8°C
Storage and Stability Opened	12 hours when thawed and refrigerated at 2-8°C	Until expiration at 2-8°C

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

None Stated

L. Test Principle:

Not Applicable. This submission is for clearance of control material.

M. Performance Characteristics (if/when applicable):1. Analytical performance:*a. Precision/Reproducibility:*

Not Applicable

b. Linearity/assay reportable range:

Not applicable. The assay is intended for qualitative use.

c. Traceability (controls, calibrators, or method):

Traceability:

The Ischemia Assay Verification Set (AVS) is manufactured from commercially available pooled serum (off-the-clot), cobalt chloride and EDTA. Each material is tested individually for expected value. The final formulation is standardized for assay level internally using the Ischemia Technologies Albumin Cobalt Binding (ACB®) Test with known concentrations of cobalt chloride in serum and EDTA.

The serum is tested in duplicate using the ACB Test on the Cobas Mira Plus analyzer. Values for serum must fall within 60-100U/mL. Cobalt chloride and EDTA stock solutions are prepared in volume ranges from 0.5 µL to 10 µL and tested, in duplicate, using the ACB Test on a calibrated analyzer. The average ACB value is plotted against the volume of added cobalt chloride and EDTA and the curve fit must be linear with an R^2 value of ≥ 0.95 .

The AVS formulation is evaluated by running the ACB Test, in duplicate, on increasing volumes of cobalt chloride in a serum and EDTA matrix using a calibrated analyzer. Average values are plotted against the volume of cobalt chloride and the curve generated must be linear with an R^2 value of ≥ 0.95 . Initial target values are then confirmed internally prior to bulk formulation filling.

Each of the 20 AVS levels is dispensed from the bulk formulation in 0.5 mL aliquots and in appropriate dilution level into Micro

Tubes with caps labeled with lot number and assay level (1-20).
Product is boxed and placed in a -70° C freezer.

Controls and Calibrators:

There are no additional controls or calibrators used for AVS other than those cleared for use under the Albumin Cobalt Binding Test 510(k) s

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.