

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

A. 510(k) Number:

k063398

B. Purpose for Submission:

New device

C. Measurand:

Quality control material for lead in whole blood

D. Type of Test:

Not applicable

E. Applicant:

Bionostics, Inc.

F. Proprietary and Established Names:

ESA LeadCare II Lead Control

G. Regulatory Information:

1. Regulation section:

21 CFR §862.3280

2. Classification:

Class I, (reserved)

3. Product code:

DIF

4. Panel:

91, Toxicology

H. Intended Use:

1. Intended use(s):

See Indications for use below

2. Indication(s) for use:

ESA Biosciences LeadCare II Control is intended to be used to monitor and evaluate the analytical performance of the ESA Biosciences LeadCare II Analyzer for the measurement of lead in blood. The use of quality control materials is indicated as an objective assessment of the precision of methods and techniques in use and is an integral part of good laboratory practice. The two levels of lead provided by the controls allow performance monitoring within the clinically important range.

3. Special conditions for use statement(s):

For prescription use

4. Special instrument requirements:

ESA Biosciences LeadCare II Lead Analyzer

I. Device Description:

The ESA LeadCare II Control contains two levels of quality control material. The control materials are an aqueous solution containing bovine albumin, lead, buffers, preservative and dye in concentrations determined optimal for the LeadCare II System. The controls are provided ready-to-use.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Kaulson Labs LeadCare Lead Control

2. Predicate 510(k) number(s):

k830234

3. Comparison with predicate:

Similarities/Differences		
Item	Device	Predicate
Name	LeadCare II Lead Control	Kaulson Labs LeadCare Lead Control
Description	Aqueous solution containing bovine albumin, salts, preservatives and dye	Lyophilized whole bovine blood with measured water for dilution
Intended Use	LeadCare II Lead Controls are intended for use as a quality control to monitor the precision of measurement and verify the performance of the ESA Biosciences LeadCare II System at two distinct levels within the measurement range.	Same
Levels	2	2
Analytes	Lead	Lead

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

FDA 21 CFR 820 Quality System Regulation

Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostics medical devices

ISO 13485:2003; Quality Systems. Medical Devices – Quality Management Systems Requirements for regulatory purposes.

ISO 14971:2000. Medical Devices: Application of risk analysis to medical devices.

ISO 15223:2002. Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied.

Points to consider guidance document on assayed and unassayed quality control material. US FDA, Feb 3 1999

Use of Symbols on Labels and in Labeling of In Vitro Diagnostic Devices Intended for Professional Use, US FDA, Nov 30, 2004

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

c. Traceability, Stability, Expected values (controls, calibrators, or methods):

The ESA Control is prepared by gravimetrically adding Lead AA standards to a buffered solution at known concentrations. The concentrations are then confirmed by Graphite Furnace Atomic Absorption method.

Value assignment is determined based upon replicate assays of representative samples of control on multiple instruments and lots of measurement kits.

Stability:

Real time stabilities studies have been conducted. Protocols and acceptance criteria were described and found to be acceptable. The stability is listed below:

Open vial stability is 2 months at 2 to 8°C

Closed vial stability is 18 months at 15 to 27°C

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 assayed value range for each control is provided on the vial label. The target value ranges are expected to be within the following: level 1 6.0-10.0 µg/dL; level II 22.0 to 28.0 µg/dL.

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.