

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

A. 510(k) Number:

K042336

B. Purpose for Submission:

To seek clearance of a new whole blood hematology/glucose control.

C. Measurand:

Hemoglobin, hematocrit and glucose

D. Type of Test:

Assayed whole blood control

E. Applicant:

Bio-Rad Laboratories

F. Proprietary and Established Names:

Meter Trax Control

G. Regulatory Information:

1. Regulation section:

21 CFR 864.8625

21 CFR 862.1660

2. Classification:

Class II

3. Product code:

JPK

JJY

4. Panel:

81 Hematology

H. Intended Use:

1. Intended use(s):

Meter Trax is an assayed whole blood control used in monitoring the precision of laboratory testing procedures for hemoglobin, hematocrit and glucose.

2. Indication(s) for use:

3. Special conditions for use statement(s):

4. Special instrument requirements:

I. Device Description:

Meter Trax is a tri-level (low, medium, high) liquid suspension of stabilized human red blood cell components with added constituents of animal origin, chemicals, stabilizers, and preservatives.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Meter Trax

Bio-Rad Laboratories (formerly Hematronix, Inc.)

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

K904461

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Matrix	Human whole blood based	same
Form	Liquid	same
Analytes	Hemoglobin, hematocrit, glucose	same

Differences		
Item	Device	Predicate
Intended use	Meter Trax is an assayed whole blood control intended for use in monitoring the precision of laboratory testing procedures for glucose, hemoglobin, and hematocrit.	Meter Trax™ is intended for use as a whole blood reference control for glucose, hemoglobin, and hematocrit.
Stabilizers	Contains stabilizers	Does not contain stabilizers

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

L. Test Principle:

M. Performance Characteristics (if/when applicable):

1. Analytical performance:
 - a. *Precision/Reproducibility:*
 - b. *Linearity/assay reportable range:*
 - c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*
 - d. *Detection limit:*
 - e. *Analytical specificity:*
 - f. *Assay cut-off:*

2. Comparison studies:

a. *Method comparison with predicate device:*

b. *Matrix comparison:*

3. Clinical studies:

a. *Clinical Sensitivity:*

b. *Clinical specificity:*

c. Other clinical supportive data (when a. and b. are not applicable):

4. Clinical cut-off:

5. Expected values/Reference range:

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.