

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

A. 510(k) Number:

k050721

B. Purpose for Submission: New device

C. Measurand: WBC (GB), NRBC (ERB) %, NRBC (ERB)#

D. Type of Test: Not applicable

E. Applicant:

HORIBA ABX, Inc.

F. Proprietary and Established Names:

ABX Erytrol

G. Regulatory Information:

1. Regulation section:

864.8625 Hematology Quality Control Mixture

2. Classification:

Class II

3. Product code:

JPK

4. Panel:

81 Hematology

H. Intended Use:

1. Intended use(s):

ABX Erytrol is a tri-level control designed for use in monitoring the accuracy and

precision of the HoribaABX hematology blood cell counters for NRBC parameter.

2. Indication(s) for use:

Same

3. Special conditions for use statement(s):

None

4. Special instrument requirements:

For use with ABX Hematology Analyzers

I. Device Description:

The ABX Erytrol is an in-vitro diagnostic blood control composed of human erythrocytes and mammalian leukocytes in a plasma-like fluid with preservatives. The ABX erythrol is composed of stable materials that provide a means of monitoring the performance of ABX hematology analyzers offering the nucleated red blood cell count (NRBC) parameter.

J. Substantial Equivalence Information:

1. Predicate device name(s):

PENTRA 5D Hematology Control, R & D Systems, Inc.

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

K003534

3. Comparison with predicate:

Similarities		
Item	PENTRA 5D	ABX ERYTROL
Intended Use	For 5 diff parameters	For NRBC parameters
Summary	Similar	Similar
Principle	Similar	Similar
Reagents	Human RBCs Different species of WBC Platelets	Human RBCs Different species of WBC
Storage	Similar	Similar

Similarities		
Item	PENTRA 5D	ABX ERYTROL
Stability	Closed: 74 days shelf 60 customer Open: 14 days	Similar

Differences		
Item	Device	Predicate
Parameters	5 part diff	NRBC

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

Not applicable

L. Test Principle:

Not applicable

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

A non-clinical study testing 3 validation lots to determine precision and stability was found to be within acceptable limits

b. Linearity/assay reportable range:

Not applicable

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

A non-clinical study testing 3 validation lots to determine precision and stability was found to be within acceptable limits

d. Detection limit:

Not applicable

e. Analytical specificity:

Not applicable

f. Assay cut-off:

Not applicable

2. Comparison studies: Not applicable

a. *Method comparison with predicate device:*

b. *Matrix comparison:*

3. Clinical studies: Not applicable

a. *Clinical Sensitivity:*

b. *Clinical specificity:*

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

4. Clinical cut-off: Not applicable

5. Expected values/Reference range:

Assigned values are presented as a Mean Value that is derived from replicate testing on instruments operated and maintained according to the manufacturer instructions. The Range is an estimate of variation between laboratories and also takes into account expected biological variability of the control material.

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.