

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

A. 510(k) Number:

K041457

B. Purpose for Submission:

New device

C. Analyte(s):

BASO, EOS, HCT, HGB, LYMPH, MCH, MCHC, MCV, MONO,
MPV, NEU, PLT, RBC, RDW, GRAN, MID, and WBC (NOC, WIC, WOC)

D. Type of Test:

N/A

E. Applicant:

Bio-Rad Laboratories

F. Proprietary and Established Names:

Liquichek™ Hematology Control (A), (Low, Normal, High); Hematology Quality Control (QC) Mixture

G. Regulatory Information:

1. Regulation section: 21 CFR 864.8625 – Hematology Quality Control (QC) Mixture
2. Classification: Class II
3. Product Code(s): JPK - Hematology QC Mixture; JCN – Cell Counter Control, Normal/Abnormal
4. Panel: Hematology (81)

H. Intended Use:

1. Intended use(s): Liquichek™ Hematology Control (A) is an assayed whole blood control for evaluating precision of hematology

instruments that provide a WBC differential.
[See **C. Analyte(s)** above]

2. Indication(s) for use: Same as Intended Use.
3. Special condition for use statement(s): N/A
4. Special instrument Requirements: Assayed for use on the Abbott Cell-Dyn 3200, 3500 and 3700 instruments.

I. Device Description:

Liquichek™ Hematology Control (A) is a tri-level whole blood hematology control for *in vitro* diagnostic use in evaluating precision of hematology instruments that provide a white blood cell differential. It is a suspension of stabilized human white cells, lysable human red cells, simulated human platelets of animal origin, stabilizers and preservatives.

J. Substantial Equivalence Information:

1. Predicate device name(s): Bio-Rad Tri-Count 20 Hematology Whole Blood Control
2. Predicate K number(s): #K960471
3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Assay instrumentation	Automated hematology instruments	Same
Form	Liquid	Same
Matrix	Human whole blood base	Same
Levels	Tri-level	Same
Differences		
Item	Device	Predicate
Assayed for use instrument	Abbott Cell-Dyn hematology line	Coulter hematology line
Stability (Open vial) at 2 – 8° C.	(7) days	(14) days

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

L. Test Principle: Abbott Cell-Dyn instrumentation

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility: Replicates of the tri-level control were run at (4) different labs, on (2) members of the Cell-Dyn line of instruments. Results for all parameters ranged 0 – 10% CV.

b. Linearity/assay reportable range: N/A

c. Traceability, Stability, Expected values (controls, calibrators, or method): Value assignment was performed using the Abbott Cell-Dyn counting methods.

d. Detection limit: N/A

e. Analytical specificity: N/A

f. Assay cut-off: N/A

2. Comparison studies: N/A

a. Method comparison with predicate device:

b. Matrix comparison:

3. Clinical studies: N/A

a. Clinical sensitivity:

b. Clinical specificity:

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

4. Clinical cut-off: N/A

5. Expected values/Reference range: N/A

N. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.

