

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY**

A. 510(k) Number:

k091303

B. Purpose for Submission:

Modification of a cleared device

C. Measurand:

WBC, LYMPH, MONO, MID, GRAN, RBC, HGB, HCT, MCH, MCHC, MCV, RDW, PLT and MPV

D. Type of Test:

Assayed quality control material

E. Applicant:

Bio-Rad Laboratories

F. Proprietary and Established Names:

Liquichek Hematology-16 Control LV

G. Regulatory Information:

1. Regulation section:
21 CFR 864.8625; Hematology quality control
2. Classification:
Class II
3. Product code:
JPK; Mixture, Hematology Quality Control
4. Panel:
Hematology 81

H. Intended Use:

1. Intended use(s):
Liquichek Hematology-16 Control LV is intended for use as an assayed hematology control to monitor the precision of hematology analyzers that measure the following parameters: GRAN (Granulocytes), HCT (Hematocrit), HGB (Hemoglobin), LYMPH (Lymphocytes), MCH (Mean Corpuscular Hemoglobin), MCHC (Mean Corpuscular Hemoglobin Concentration), MCV (Mean Corpuscular Volume), MID (Mid-Sized Cells), MONO (Monocytes), MPV (Mean Platelet Volume), PLT (Platelets), RBC Red Blood Cells), RDW (Red Blood Cell Distribution Width), and WBC (White Blood Cells).
2. Indication(s) for use:
Same as intended use
3. Special conditions for use statement(s):
Not applicable
4. Special instrument requirements:
Not applicable

I. Device Description:

This product is a suspension of stabilized lysable human erythrocytes, simulated platelet components, simulated white cells and constituents of animal origin in a medium containing stabilizers.

J. Substantial Equivalence Information:

1. Predicate device name(s):
Liquichek Hematology-16 Control (formerly known as TRI-COUNT 16)
2. Predicate 510(k) number(s):
k902389
3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended Use	Liquichek Hematology-16 Control LV is intended for use as an assayed hematology control to monitor the precision of hematology analyzers that measure the following parameters: GRAN (Granulocytes), HCT (Hematocrit), HGB (Hemoglobin), LYMPH (Lymphocytes), MCH (Mean Corpuscular Hemoglobin), MCHC (Mean Corpuscular Hemoglobin Concentration), MCV (Mean Corpuscular Volume), MID (Mid-Sized Cells), MONO (Monocytes), MPV (Mean Platelet Volume), PLT (Platelets), RBC Red Blood Cells), RDW (Red Blood Cell Distribution Width), and WBC (White Blood Cells).	Liquichek Hematology-16 Control is a hematology reference control used in monitoring determinations of blood cell values on cell counters.
Form	Liquid	Same
Matrix	Suspension containing blood cells	Same
Preservatives	Contains preservatives	Same
Storage (unopened)	160 days at 2°C to 8°C	Same
Open vial claim	21 days at 2°C to 8°C	Same
Analytes	GRAN (Granulocytes), HCT (Hematocrit), HGB (hemoglobin), LYMPH (Lymphocytes), MCH (Mean Corpuscular Hemoglobin), MCHC (Mean Corpuscular Hemoglobin Concentration), MCV (Mean Corpuscular Volume), MID (mid-Sized Cells)/ Mono (Monocytes), MPV (Mean Platelet Volume), PLT (Platelets), RBC (Red Blood Cells), RDW (Red Blood Cells Distribution Width), WBC (White Blood Cells)	Same

Differences		
Item	Device	Predicate
Fill Volume	1.5 mL	3.0 mL
Vial Type	Glass vials with screw caps	Glass tubes with pierceable caps

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

CLSI EP5-A2, Evaluation of Precision Performance of Quantitative Measurement Methods

L. Test Principle:

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 practices. Three levels of control are available to allow monitoring of performance.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

Each level of control was tested two times per day, in duplicate, for 20 days as outlined in the CSLI EP5-A2 guideline. The total precision standard deviations for Liquichek Hematology-16 Control LV (Table 1) were compared to the instrument manufacturer precision standard deviation (Table 2) and the statistical p-values were calculated utilizing a chi-square test. The observed differences between the study precision results and the instrument manufacturer precision claims are considered statistically significant when the p-values are < 0.05. The p-values obtained from this study are > 0.05 (Table 3), which indicates that the observed differences are not statistically significant.

Table 1: Total precision standard deviation for Liquicheck Hemtology-16 Control LV

Parameter	RBC Cells/μL	Hbg g/dL	MCV fL	RDW %	PLT Cells/μL	MPV fL	WBC Cells/μL	LY%	MO%	GR%
Low	0.025	0.076	0.542	0.198	1.654	0.124	0.096	1.243	1.206	0.946
Normal	0.027	0.103	0.502	0.153	4.861	0.062	0.133	1.066	0.906	0.794
High	0.029	0.116	0.560	0.309	11.089	0.075	0.227	0.643	0.382	0.756

Table 2: Instrument Manufacturer Precision Standard Deviation

Parameter	RBC Cells/μL	Hbg g/dL	MCV fL	RDW %	PLT Cells/μL	MPV fL	WBC Cells/μL	LY%	MO%	GR%
Low	0.040	0.120	0.720	0.348	3.780	0.198	0.170	2.964	1.136	1.500
Normal	0.040	0.120	0.720	0.318	9.900	0.198	0.170	2.438	0.100	2.138
High	0.042	0.140	0.768	0.322	17.435	0.198	0.362	2.059	0.100	2.707

Table 3: Statistical “p” Values for Total Precision SD

Parameter	RBC Cells/μL	Hbg g/dL	MCV fL	RDW %	PLT Cells/μL	MPV fL	WBC Cells/μL	LY%	MO%	GR%
Low	1.0000	1.0000	0.9818	1.0000	1.0000	1.0000	1.0000	1.0000	0.2247	1.0000
Normal	0.9998	0.9499	0.9976	1.0000	1.0000	1.0000	0.9985	1.0000	0.1925	1.0000
High	0.9997	0.9841	0.9931	0.6311	1.0000	1.0000	1.0000	1.0000	0.9864	1.0000

b. *Linearity/assay reportable range:*

Not Applicable

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

Stability studies were performed to determine the open vial and shelf life

stability for the Liquichek Hematology-16 Control LV. Two lots of data are provided for each study. These studies are performed in such a manner as to mimic the handling of product in the customer's hands following opening of these products and their preparation for use. The open vial study time is typically defined to be at least 20% longer than the claimed open vial stability for the product and tested at least at four time points: at the beginning at the end and two time points during the middle of the study (T-zero, T- M1, T-M2 and T-Final + 20%). The acceptance criterion is generally defined as the T-Final + 20% being within the expected ranges.

Open Vial Stability: All parameters are stable for 21 days when stored at 2°-8°C.

Shelf life stability: All parameters are stable for 160 days at 2 -8° C.

The review of the data was within acceptable limits.

Value Assignment: The mean values printed in the Liquichek Hematology-16 Control LV package insert are derived from replicate analyses and are specific for each lot of product. The tests listed are performed by manufacturer or independent laboratories using a representative sampling of each product. Laboratory results may vary from the listed values. Variations over time and between laboratories may be caused by differences in laboratory technique, instrumentation calibrating methods, reagents or by any stated limitations for this product. It is recommended that each laboratory establish its own means and acceptable ranges with each lot of Liquichek Hematology-16 Control LV.

- 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:
Expected values are provided in the Package Insert accompanying the product.

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.