BIO·RAD

Liquichek™ Hematology Control (A)
Low, Normal and High

REF				CE	IVD	EXP 2019-07-05	LOT	BR6230		
	865	Trilevel	12 x 3 mL						Low	BR6231
	866	Low	4 x 3 mL						Normal	BR6232
	867	Normal	4 x 3 mL						High	BR6233
	868	High	4 x 3 mL							
	865X	Trilevel MiniPak	3 x 3 mL							

ENGLISH

INTENDED USE
Liquichek Hematology Control (A) is an assayed whole blood control designed to monitor values on multi-parameter hematology cell counters.

SUMMARY AND 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 performance monitoring within the clinical range.

For customers in Germany: Quality control materials are required for assessment of laboratory performance as described in the "Guideline for Quality Assurance of Medical Laboratory Examinations following the German Medical Association" (Rili-BÄK regulation).

REAGENT
This product contains human erythrocytes, mammalian leukocytes and mammalian platelets suspended in a plasma-like fluid with preservatives.

STORAGE AND STABILITY
This product will be stable until the expiration date when stored unopened at 2 to 8°C. Once opened, this product will be stable for 8 days when handled properly and stored tightly capped at 2 to 8°C.

Protect tubes from OVERHEATING and FREEZING. Store product upright when not in use.

This product is shipped under refrigerated conditions.

PROCEDURE
This product should be treated and analyzed the same as patient specimens and run in accordance with the instructions accompanying the instrument, kit, or reagent being used.

1. Remove tubes from the refrigerator and allow to warm to room temperature (15 to 30°C) for 15 minutes before mixing.
2. To mix, hold a tube horizontally between the palms of the hands. **Do not pre-mix on a mechanical mixer.**
   a. Roll the tube back and forth for 20 to 30 seconds; occasionally invert the tube. Mix vigorously, but do not shake.
   b. Continue to mix in this manner until the red cells are completely suspended. Tubes stored for a long time may require extra mixing.
   c. Gently invert the tube 8 to 10 times immediately before sampling.
3. Analyze the sample as instructed in the Quality Control section of the Operator's Manual for your instrument.
4. After sampling:
   a. If tube has been opened for sampling, clean residual material from cap and tube rim with a lint-free tissue. Replace the cap tightly.
   b. Return tubes to refrigerator within 30 minutes of use.

Dispose of any discarded materials in accordance with the requirements of your local waste management authorities. In the event of damage to packaging, contact the local Bio-Rad Laboratories Sales Office or Bio-Rad Laboratories Technical Services.

LIMITATIONS
1. This product should not be used past the expiration date.
2. This product is not intended for use as a standard.
3. After mixing, this product should be similar in appearance to fresh whole blood. In unmixed tubes, the supernatant may appear cloudy and reddish. This is normal and does not indicate deterioration. Other discoloration, very dark red supernatant or unacceptable results may indicate deterioration. **Do not use this product if deterioration is suspected.**
4. Incomplete mixing of a tube prior to use invalidates both the sample withdrawn and any remaining material in the tube.

ASSIGNMENT OF VALUES
Assigned values are presented as a Mean and Range. The Mean is derived from replicate testing using the manufacturer's recommended reagents on instruments operated and maintained according to the manufacturer's instructions. The Range is an estimation which takes into account inherent imprecision of the method, expected biological variability of the control material, and potential variations between laboratories. Reagent differences, instrument maintenance, calibration and operating technique may contribute to inter-laboratory variation.

Assay values on a new lot of control should be confirmed before the new lot is put into routine use. Test the new lot when the instrument is in good working order and quality control results on the old lot are acceptable. The laboratory's recovered mean should be within the assay range. It is recommended that each laboratory establish its own means and acceptable ranges and use those provided only as guides.

Refer to *www.qcnet.com* for insert update information.

SPECIFIC PERFORMANCE CHARACTERISTICS
This product is a stabilized liquid product manufactured under rigid quality control standards. To obtain consistent tube-to-tube assay values, this product requires proper storage and handling as described.

REF	CE	IVD	EXP	LOT	⚠	Consult	Temperature	Mfd. For	EC REP
Catalog Number	European Conformity	*In Vitro* Diagnostic Medical Device	Use by (2019-07-05)	Lot Number	Caution, Consult Accompanying Documents	Consult Instructions for Use	Temperature Limitation	Manufactured For	Authorized Representative

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⚠ WARNING

GLOSSARY

PARAMETERS

BASO (Basophils)
EOS (Eosinophils)
GRAN (Granulocytes)
HCT (Hematocrit)
HGB (Hemoglobin)
LYMPH (Lymphocytes)
MCH (Mean Corpuscular Hemoglobin)

MCHC (Mean Corpuscular
 Hemoglobin Concentration)

MCV (Mean Corpuscular Volume)

MID
MONO (Monocytes)
MPV (Mean Platelet Volume)

NEUT (Neutrophils)
NRBC (Nucleated Red Blood Cells)

NRBC/100 WBC (NRBC percent
 of WBC count)

PCT (Plateletcrit) (1)

PDW (Platelet Volume
 Distribution Width) (1)
PLT (Platelets)
PLTi (Platelets Impedance Method)

RBC (Red Blood Cells)
RBCo (Red Blood Cells, Optical)

RDW (Red Blood Cell
 Distribution Width)
WBC (White Blood Cells)
 NOC (Nucleated Optical Count)

 WIC (White Impedance Count)

 WOC (White Optical Count)

TERMS

High
Low
Mean
Normal
Range
Units