

# Liquichek™ Hematology Control (C) Low, Normal and High

<b>REF</b>	<b>904</b>	Trilevel	12 x 5 mL
	<b>905</b>	Low	4 x 5 mL
	<b>906</b>	Normal	4 x 5 mL
	<b>907</b>	High	4 x 5 mL
	<b>904X</b>	Trilevel MiniPak	3 x 5 mL



**EXP 2019-06-08**



<b>LOT</b>	1780	Low	871781
		Normal	881782
		High	861783

**ENGLISH**

**INTENDED USE**

Liquichek Hematology Control (C) is a control designed to monitor values on COULTER® hematology analyzers.

**SUMMARY AND PRINCIPLE**

It is an established laboratory practice to use a stable control to monitor the performance of diagnostic tests. This product is composed of stable materials that provide a means of monitoring the performance of hematology blood cell counters. It is sampled in the same manner as a patient specimen.

**REAGENT**

This product contains human erythrocytes, simulated leukocytes, and mammalian platelets 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 14 days or 14 thermal cycles (uses), whichever comes first, 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.

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

If instrument includes an autosampler/mixer, **mix first as directed above**, then place the tubes in a cassette and place on the instrument. 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**

- This product should not be used past the expiration date.
- This product is not intended for use as a standard.
- After mixing, this product should be similar in appearance to fresh whole blood. In unopened 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.**
- 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 on instruments operated and maintained according to the manufacturer's instructions. The Range is an estimate of variation between laboratories and also takes into account inherent imprecision of the method and expected biological variability of the control material.

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.

Assigned values are determined on well-maintained, properly calibrated instruments using the manufacturer's recommended reagents. Reagent differences, instrument maintenance, calibration and operating technique may contribute to inter-laboratory variation. For greater control sensitivity, each laboratory should establish its own mean and acceptable range and periodically reevaluate the mean. The laboratory range may include values outside of the assay range. The user may establish assay values not printed in this insert, if the control is suitable for the method.

Refer to [www.qcnet.com](http://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.



*[Signature]*  
GIÁM ĐỐC  
Phạm Thị Thu Hằng



Catalog Number



European Conformity



In Vitro Diagnostic Medical Device



Use by (2019-06-08)



Lot Number



Caution, Consult Accompanying Documents



Consult Instructions for Use



Temperature Limitation



Manufactured For



Authorized Representative



## WARNING

### ENGLISH

#### Biological source material. Treat as potentially infectious.

Each human donor unit used to manufacture this product was tested as required by FDA accepted methods. Tests results were non-reactive or negative for evidence of infection due to Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV) and Hepatitis C Virus (HCV). Each unit is also negative by a serological test for Syphilis (RPR or STS). This product may also contain other human source materials for which there are no approved tests. In accordance with good laboratory practice, all human source material should be considered potentially infectious and handled with the same precautions used with patient specimens.

Safety Data Sheet (SDS) available for professional users on [www.bio-rad.com](http://www.bio-rad.com).

### GLOSSARY

#### PARAMETERS

BA (Basophils)  
EO (Eosinophils)  
HCT (Hematocrit)  
HGB (Hemoglobin)  
LY (Lymphocytes)  
MCH (Mean Corpuscular Hemoglobin)  
  
MCHC (Mean Corpuscular Hemoglobin Concentration)  
  
MCV (Mean Corpuscular Volume)  
  
MO (Monocytes)  
MPV (Mean Platelet Volume)  
  
NE (Neutrophils)  
PCT (Plateletcrit) (1)  
PDW (Platelet Distribution Width) (1)  
  
PLT (Platelets)  
RBC (Red Blood Cells)  
RDW (Red Blood Cell Distribution Width)  
RDW-SD (RBC Distribution Width-Standard Deviation) (2)  
  
WBC (White Blood Cells)

#### TERMS

High  
Low  
Mean  
Normal  
Range  
Ratio  
Units