BIO-RAD

Liquichek™ Hematology-16T Control
Low, Normal and High

M.S.D.N: 0106619054 - C.T.T.N.H.H
CÔNG TY TNHH THƯƠNG MẠI SIXMURS HTH VIỆT NAM
Q. BẮC TỪ LIÊM - TP. HÀ NỘI

REF	**144**	Trilevel	12 x 2.5 mL	CE	IVD	EXP **2022-06-05**	LOT	94280
	144X	Trilevel MiniPak	3 x 2.5 mL					Low 94281 Normal 94282 High 94283

ENGLISH

INTENDED USE

Liquichek Hematology-16T Control is a control designed to monitor values on automated and semi-automated impedance type hematology analyzers. It can also be used for manual methods.

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, simulated 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 8ºC. Once opened, this product will be stable for 14 days when handled properly and stored tightly capped at 2 to 8ºC.

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 estimate of variation between laboratories and also takes into account inherent imprecision of the method and expected biological variability of the control material. 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	⚠			Mfd. For	EC REP	
Catalog Number	European Conformity	*In Vitro* Diagnostic Medical Device	Use by (YYYY-MM-DD)	Lot Number	Caution, Consult Accompanying Documents	Consult Instructions for Use	Temperature Limitation	Manufactured For	Authorized Representative	

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⚠ WARNING

ENGLISH

Biological source material. Treat as potentially infectious.

The human source material 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). This product may also contain other human source material 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*.

GLOSSARY

PARAMETERS

GRAN (Granulocytes)
HCT (Hematocrit)
HGB (Hemoglobin)
LYMPH (Lymphocytes)
MCH (Mean Corpuscular Hemoglobin)

MCHC (Mean Corpuscular Hemoglobin Concentration)]

MCV (Mean Corpuscular Volume)

MID
MPV (Mean Platelet Volume)

PLT (Platelets)
RBC (Red Blood Cells)
RDW (Red Blood Cell Distribution Width)
RDW-CV (RBC Distribution Width-Coefficient of Variation)

RDW-SD (RBC Distribution Width-Standard Deviation)

WBC (White Blood Cells)
W-LCC (NEUT)
W-LCR (NEUT)
W-MCC (MXD)
W-MCR (MXD)
W-SCC (LYMPH)
W-SCR (LYMPH)

TERMS

High
Instrument
Low
Mean
Normal
Parameters
Range
Units

Bio-Rad Laboratories comprehensive line of quality controls and QC data management solutions.

Autoimmune Controls
Blood Gas Controls
Cardiac Assessment Controls
Chemistry Controls
Coagulation Controls
Congenital/Pediatric Disease Controls
Diabetes/Hemoglobin Controls
Hematology Controls
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Immunoassay Controls
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