GLOCYTE®

ADVANCED INSTRUMENTS

RBC & TNC Verification & Linearity Kit

IVD CE

REF 111280 Six (6) 3.0 mL vial TNC
Six (6) 3.0 mL vial RBC

Intended use:

The GloCyte RBC & TNC Verification & Linearity Kit is a multilevel control that provides a means of measuring and verifying the performance of the GloCyte Cell Counter for CSF for total nucleated and red blood cells. Linearity combined with accuracy is used to establish the range of patient values that can be accurately reported.

Summary and principle:

CAP requirements[1] and CLIA regulations[2] both mandate that laboratories establish reportable range for each test method. It is good laboratory practice to verify reportable range at initial set up of analyzer, following significant preventative maintenance, unusual trend or shift in controls and as recommended by the instrument manufacturer.

Reagents:

The GloCyte RBC & TNC Verification & Linearity Kit is an in vitro diagnostic reagent composed of human erythrocytes suspended in a plasma-like fluid with preservatives.

Precaution: The GloCyte RBC & TNC Verification & Linearity Kit is intended for *in vitro* diagnostic use only by trained personnel.

Warning: Potential Biohazardous Material

For *in vitro* diagnostic use. Each human donor/unit used in the preparation of this product has been tested, and yielded non-reactive I negative results for all conditions referenced in 21 CFR 610.40 (a) (b), as required by the FDA. Testing was conducted using FDA-licensed tests. Additional details can be found at:

http://www.rndheme.com/TechnicalInformation.aspx

No test method can offer complete assurance that infectious agents are absent; therefore this material should be handled as potentially infectious. When handling or disposing of vials follow precautions for patient specimens as specified in the OSHA Bloodborne Pathogen Rule (29 CFR Part 1910, 1030) or other equivalent biosafety procedures.

Stability and storage:

Store the GloCyte RBC & TNC Verification & Linearity Kit upright at 2-8 °C when not in use.

Protect tubes from overheating and freezing. Unopened tubes are stable through the expiration date. Sampled product should be used immediately, then discarded.

Do not use the product if the packaging is compromised. Contact Advanced Instruments or your authorized dealer in the event of damage to the protective packaging.

Indications of deterioration:

After mixing, the GloCyte RBC & TNC Verification & Linearity Kit red cell tubes should be similar in appearance to fresh whole blood with varying concentrations of red blood cells. 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. The GloCyte RBC & TNC Verification & Linearity Kit white cell tubes are colorless and slightly cloudy. Discoloration of the tubes may indicate deterioration or contamination. Do not use the product if deterioration is suspected.

Instructions for use:

Caution: Instructions must be followed precisely to ensure reliable results.

A. Prepare GloCyte System: Check system performance according to the *GloCyte User's Guide***.**

1. Verify that the instrument reagents are not expired and that the supply is sufficient.
2. Check that background counts and control results are acceptable.
3. If the instrument is not operating properly, identify the malfunction and perform the appropriate troubleshooting procedures.
4. Verify and document that the instrument is operating properly before proceeding.

B. Mixing and handling directions:

Red Blood Cell Tubes

1. Remove tube from the refrigerator and allow to warm at room temperature (15-30 °C or 59-86 °F) for 15 minutes before mixing.
2. To mix, hold the 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 - 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. Invert the tube 8 - 10 times immediately before each sampling.

Total Nucleated Cell Tubes

1. Remove tube from the refrigerator and allow to warm at room temperature (15-30° C or 59-86 °F) for 15 minutes before mixing.
2. Mix using vortex mixer.
   a. Mix by vigorously agitating on a vortex mixer for 2 minutes to ensure complete dispersion of micro aggregates.
   b. Let sample sit undisturbed for 10 minutes to allow micro bubbles to dissipate before sampling.
   c. Invert the tube 8 -10 times immediately before each sampling.

C. Analyze GloCyte Verification & Linearity Kit:

1. Prepare the GloCyte RBC & TNC Verification & Linearity Kit for analysis exactly as a patient sample and analyze control as instructed in *GloCyte User's Guide*.
2. Test all levels from lowest concentration (Level 1) to highest concentration (Level 6).
3. Run each level a minimum of four times. Mix the tubes between runs according to the Mixing and Handling directions.

Expected results:

The GloCyte RBC & TNC Verification & Linearity Kit is prepared by precise dilutions of concentrated stock. The obtained mean will be evaluated against the expected value. The difference between the obtained values and the expected values is compared to acceptable limits. Each lab must define its own acceptable limits that can be used by the laboratory director to establish acceptable analytical performance criteria and a reportable range to ensure test results are consistent with the medical needs of the patient.

Assigned values are presented as a mean and range. The mean is derived from replicate testing of the indicated lots on multiple GloCyte Systems, operated and maintained according to the manufacturer's instructions. The range is an estimate of variation between replicates.

Limitations:

The performance of this product is assured only if it is properly stored and used as described in this insert. Incomplete mixing of a tube prior to use invalidates both the sample withdrawn and any remaining material in the tube.

Apply label here

For sales and service:

Contact your Advanced Instruments distributor.

1 College of American Pathologists, 2004, Commission on Laboratory Accreditation Inspection Checklist HEM.30250.

2 Clinical Laboratory Improvement Amendments as set forth in 42 CFR 493.1253 Standard.

 111276 Rev3

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Lot Number | Catalog Number | Use By | Manufacturer | Temperature Limit | Consult Instructions for Use

Control | For *In Vitro* Diagnostic Use | European Conformity | Biohazard | Authorized Representative | Single Use Only

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