

Hemolyzer-Calibrator

(Hematology Calibrator)



Order information:

| Catalog-No. | Content |
|-------------|----------|
| HE3601 | 2 x 3 ml |

Intended use:

Hemolyzer-Calibrator is designed for use in the calibration of hematology analyzers. Please refer to the assay table for specific instrument models.

Summary and principle:

Hematology analyzers require periodic calibration in order to generate accurate patient results. This calibrator is a stable, whole blood preparation that can be used to verify and adjust calibration of select hematology instruments. Calibrator values for Hemolyzer-Calibrator are derived from replicate testing on instruments operated and maintained according to the manufacturer's instructions. Instruments are calibrated with whole blood using values determined by reference methods.

Composition:

Hemolyzer-Calibrator is an in vitro diagnostic reagent composed of human erythrocytes, mammalian leukocytes and mammalian platelets suspended in a plasma-like fluid with preservatives.

Storage and Stability:

Control is ready for use

Store Hemolyzer-Calibrator upright at 2 - 8° C (35 - 46° F) when not in use.

Unopened tubes are stable until the expiration date. Opened tubes are stable for 7 days, provided they are handled properly.

Protect tubes from overheating and freezing.

Indications of deterioration:

After mixing, 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 the product if deterioration is suspected.**

Instructions for use:

A. Mixing and handling directions:

- Remove tubes/vials from the refrigerator and allow to warm at room temperature (15 - 30°C or 59 - 86°F) for 15 minutes before mixing.
- To mix, hold a tube/vial horizontally between the palms of the hands. **Do not pre-mix on a mechanical mixer.**
 - Roll the tube/vial back and forth for 20 - 30 seconds; occasionally invert the tube/vial. Mix vigorously but do not shake.
 - Continue to mix in this manner until the red cells are completely suspended. Tubes/vials stored for a long time may require extra mixing.
 - Gently invert the tube/vial 8 - 10 times immediately before running each sample.
- After sampling:
 - Automatic Sample Handling: Remove the tube/vial from the sample handler immediately after sampling.
 - Manual Sample Handling: Carefully wipe the tube/vial rim and cap with a lint-free tissue and replace the cap.
- Return tubes/vials to refrigerator within 30 minutes of use.

B. Analyze Calibrator:

- Prime the instrument once by aspirating calibrator sample. Discard the result.
- Analyze calibrator according to the calibration procedure in the Operator's Manual for your instrument.
- Compare the mean value for each parameter to the assigned value.
 - If the difference is within the Range, calibration is optional.
 - If the difference is not within the Range, calibration may be needed.
- Ranges given on the assay sheet are intended as guidelines for evaluating instrument calibration. Acceptable ranges should be established by each laboratory. If the calibrator recovered data is outside the range found on the assay sheet with stable control results, interlaboratory QC and/or Proficiency Testing reports that have excellent peer group agreement, this may indicate possible product damage. **Do not use the product if deterioration is suspected.**

C. Adjust instrument calibration and verify results:

- Calibrate the instrument by using the calibration adjustment procedures described in the Operator's Manual for your instrument.
- Verify calibration by analyzing calibrator and repeat step 3 under "Analyze Calibrator".
- Confirm calibration by running quality control material.

Expected Results:

Verify that the lot number on the tube/vial matches the lot number on the table of assay values. Assay values are determined on well-maintained, properly calibrated instruments using the instrument manufacturer's recommended reagents.

Reference Methods:

- WBC: A series of 1:500 dilutions are made with calibrated glassware. Counting is performed on a Coulter Counter Z series instrument. All counts are corrected for coincidence
- RBC: A series of 1:50,000 dilutions are made with calibrated glassware. Counting is performed on a Coulter Counter Z series instrument. All counts are corrected for coincidence
- HGB: Hemoglobin value is determined by spectrophotometric procedure according to CLSI Standard H15-A3 and is traceable to ICSH/WHO International Haemoglobinocyanide Standard.
- HCT: Packed cell volume (PCV) is measured by the microhematocrit procedure according to CLSI Standard H7 A3. No correction is made for trapped plasma.
- PLT: A series of 1:126 dilutions are made using calibrated glassware in 1% ammonium oxalate. Platelets are counted using a hemocytometer and phase contrast microscopy.

Performance Limits:

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/vial prior to use invalidates both the sample withdrawn and any remaining material in the tube/vial.

Notes:

For in vitro diagnostic use only.

For trained laboratory professional only.

WARNING - POTENTIAL BIOHAZARDOUS MATERIAL

The product contains human-sources and/or potentially infectious components. Each human donor/unit used in the preparation of this product has been tested by a FDA licensed method/test and found to be negative or non-reactive for the presence of HBsAg, Anti-HCV, NAT testing for HIV-1, HCV (RNA) and HIV-1/2. Each unit is also negative by a serological test for Syphilis (RPR or STS). Because no test method can offer complete assurance that infectious agents are absent, 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

Exercise the normal precautions required for handling all laboratory reagents.

Disposal:

Please note the legal regulations.