SIEMENS

CE

ADVIA® 360
ADVIA® 560
Calibrator

HEMATOLOGY CALIBRATOR

CALIBRATOR

CONTENTS

SMN 11170852

INTENDED USE

ADVIA® 360/560 Calibrator is designed for use in the calibration of ADVIA 360 and ADVIA 560 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 ADVIA 360 and ADVIA 560 hematology instruments.

Calibrator values for ADVIA 360/560 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.

REAGENTS

ADVIA 360/560 Calibrator is an *in vitro* diagnostic reagent composed of human erythrocytes, mammalian leukocytes and mammalian platelets suspended in a plasma-like fluid with preservatives.

PRECAUTIONS

ADVIA 360/560 Calibrator is intended for ***in vitro*** **diagnostic use** only by trained personnel.

WARNING

Warning! Potential Biohazard

Contains human source material.

Caution: *All products containing human source material should be treated as potentially infectious. Source material from human blood from which this product was derived was found negative when tested in accordance with current FDA required tests described in 21 CFR 610.40(a) and (b). No known test methods can offer assurance that products derived from human sources will not transmit infectious agents; this material should be handled using good laboratory practices and universal precautions.*

STABILITY AND STORAGE

Store ADVIA 360/560 Calibrator upright at 2–8°C (35–46°F) when not in use. **Protect tubes/vials from overheating and freezing.** Unopened tubes/vials are stable through the expiration date. Opened tubes/vials are stable for 7 days, provided they are handled properly.

INDICATIONS OF DETERIORATION

After mixing, product should be similar in appearance to fresh whole blood. In unmixed tubes/vials, 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:

1. 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.
2. To mix, hold a tube/vial horizontally between the palms of the hands. **Do not pre-mix on a mechanical mixer.**
   a) Roll the tube/vial back and forth for 20–30 seconds; occasionally invert the tube/vial. Mix vigorously but do not shake.
   b) Continue to mix in this manner until the red cells are completely suspended. Tubes/vials stored for a long time may require extra mixing.
   c) Gently invert the tube/vial 8–10 times immediately before running each sample.
3. After sampling carefully wipe the tube/vial rim and cap with a lint-free tissue and replace the cap.
4. Return tubes/vials to refrigerator within 30 minutes of use.

B. Analyze Calibrator:

1. Prime the instrument once by aspirating calibrator sample. Discard the result.
2. Analyze calibrator according to the calibration procedure in the Operator's Manual for your instrument.
3. Compare the mean value for each parameter to the assigned value.
   a) If the difference is within the range, calibration is optional.
   b) If the difference is not within the range, calibration may be needed.

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C. 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, inter laboratory 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.**

D. Adjust instrument calibration and verify results:

1. Calibrate the instrument by using the calibration adjustment procedures described in the Operator's Manual for your instrument.
2. Verify calibration by analyzing calibrator and repeat step 3 under “Analyze Calibrator”.
3. 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

1. **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
2. **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
3. **HGB:** Hemoglobin value is determined by spectrophotometric procedure according to CLSI Standard H15-A3 and is traceable to ICSH/WHO International Haemiglobincyanide Standard.
4. **HCT:** Packed cell volume (PCV) is measured by the microhematocrit procedure according to CLSI Standard H7-A3. No correction is made for trapped plasma.
5. **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.

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

TECHNICAL ASSISTANCE AND CUSTOMER SERVICE

For customer support, please contact your local technical support provider or distributor.
www.siemens.com/diagnostics

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