



Clinical Diagnostic Solutions, Inc.  
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Plantation, FL 33313

## Hematology Calibrator

### INTENDED USE

CDS Hematology Calibrator is manufactured for calibration of multi-parameter hematology analyzers for WBC, RBC, Hgb, MCV, Plt and MPV, as applicable to the analyzer system.

### For *In Vitro* diagnostic use.

### SUMMARY AND PRINCIPLES

Multi-parameter hematology analyzers require periodic calibration in order to produce accurate results on patient samples. Calibration may be accomplished by transferring calibration factors to the analyzer through fresh blood samples that have been assayed by reference methods. However, a more direct and convenient approach is to use a calibrator material such as CDS Hematology Calibrator, having system-specific assigned values, derived from a carefully calibrated analyzer or group of analyzers.

CDS Hematology Calibrator assigned values are derived from replicate analyses on whole blood calibrated hematology analyzers (see reference procedures). Replicate analyses are performed on the user's analyzer and calibration factors are computed by comparing recovered values and assigned values. The CDS Hematology Calibrator values are then divided by these determined factors to provide calibration settings for making adjustments to the instrument. Hct, MCH, MCHC, RDW and the WBC differential parameters do not require calibration.

### REAGENTS

CDS Hematology Calibrator contains stabilized human red blood cells, mammalian and simulated white blood cells, and a platelet component in a preservative medium.

### WARNING - POTENTIAL BIOHAZARDOUS MATERIAL

Each donor unit used in the preparation of this material was tested by an FDA approved method for the presence of antibody to Human Immunodeficiency Virus (HIV) as well as for Hepatitis B virus surface antigen and found to be negative (were not repeatedly reactive). Because no test method can offer complete assurance that Hepatitis B virus, HIV, or other infectious agents are absent, this specimen/reagent should be handled at biosafety level 2, as recommended for any potentially infectious human serum or blood specimen by the Centers for Disease Control/National Institutes of Health manual "Biosafety in Microbiological and Biomedical Laboratories", 1988.

### FOR IN VITRO DIAGNOSTIC USE WITH AUTOMATED AND SEMI-AUTOMATED HEMATOLOGY ANALYZERS AND CDS REAGENT SYSTEMS.

### STORAGE AND STABILITY

CDS Hematology Calibrator is stable through the expiration date when stored at 2° to 10° C. After opening, CDS Hematology Calibrator is stable throughout the open-vial dating, as indicated on the assay sheet. The product should be stored at 2° to 10° C when not in use.

Storage of product with cap down (inverted) might require additional mixing for complete resuspension of cellular components prior to use.

### INDICATIONS OF INSTABILITY OR DETERIORATION

Inability to obtain expected values or gross hemolysis (darkly-colored supernatant) is indicative of deterioration of the product. Light pink supernatant is normal for this product.

**Do not use if deterioration is suspected.** Contact CDS Customer Service at 800-453-3328 for assistance.

### INSTRUCTIONS FOR USE

1. Perform instrument start-up and routine cleaning procedures as defined in the instrument manufacturer's operator manual (i.e., blood sampling valve, counting apertures).
2. Warm CDS Hematology Calibrator to ambient temperature, (18-32°C), by allowing the closed vial(s) to stand 10-15 min.
3. Mix by rolling the tube gently between the palms of the hand eight (8) times, then invert the tube and repeat. Mix by inversion an additional eight (8) times to completely resuspend the blood cell components. **DO NOT MIX MECHANICALLY.**
4. Prime the instrument by aspirating a fresh blood sample twice. Disregard the results.
5. Verify instrument precision. Refer to operator's manual for instructions and specifications.
6. Analyze CDS Hematology Calibrator at least 11 times, discarding the first result. (For auto-calibration, refer to procedure in the user's manual). Record the values recovered on the remaining 10 samples.
7. Calculate the mean for each parameter.
8. Compare the results of your calculations to the assigned values listed for your instrument type in the CDS Hematology Calibrator assigned value table.
  - a. If the difference between your recovered mean values and the system values are less than the listed tolerance limits, the instrument does not require calibration.
  - b. If the difference is greater, calibrate using the system specific values.
9. Calibration of the specific parameter(s) should be done in accordance with the procedure in your instrument manual. Calibration may not be required for all parameters.
10. Verify calibration by analyzing CDS Hematology Calibrator three additional times and repeat steps 7 and 8.
11. For further assistance, please contact your local distributor.

### PRECAUTIONS

- This product should not be disposed in general waste, but should be disposed with infectious medical waste. Disposal by incineration is recommended.
- This product is intended for use as supplied. Adulteration by dilution or addition of any materials to the product as supplied invalidates any diagnostic use of the product.

### REFERENCE PROCEDURES

**WBC-** A series of 1:500 dilutions are made using class A glassware. The lytic reagent is placed in the initial dilution flask before diluting to volume. The diluting agent is an isotonic solution for Beckman Coulter® instruments. The samples are counted on a Beckman Coulter Counter Z-type instrument.

**RBC-** A series of 1:50,000 dilutions are made using class A glassware. The diluting agent is an isotonic solution for Beckman Coulter® series instruments. The samples are counted on a Beckman Coulter Counter Z-type instrument.

**Hgb-** Hemoglobin concentration is determined by converting hemoglobin to hemoglobincyanide (HiCN) and measuring absorbance at 540 nm according to NCCLS H15-A2 and ICSH recommendations. Hemoglobin concentration is calculated using millimolar absorption coefficient of 11.0.

**HCT-** Microhematocrit values are performed in replicate on each sample, with capillary tubes filled and centrifuged according to the NCCLS H7-A2 document. K3EDTA is used as the anticoagulant for collection of fresh specimens. The packed cell volume, or hematocrit, is read directly using a precision metric scale. No correction is made for trapped plasma.

**Plt-** A series of 1:125 macrodilutions are prepared using class A glassware in 1% Ammonium Oxalate. Charged hemacytometers are allowed to stand 20-30 minutes. Cells are counted using phase-contrast microscopy technique.

**MPV-** Based on a method using latex particles.

Clinical Diagnostic Solutions' customer service telephone number is: 800.453.3328, Fax: 954.791-7118, Website: [www.cdsolinc.com](http://www.cdsolinc.com).