CALIBRATOR PACKAGE INSERT

INTENDED USE
MD CAL-KIT is designed for use in the calibration of MASCOT MD SERIES hematology instruments. Values are provided for WBC, RBC, HGB, MCV, and PLT.

SUMMARY AND PRINCIPLE
The WBC, RBC, HGB, MCV and PLT parameters on hematology instruments require calibration on a periodic basis. MD CAL-KIT is a stable preparation, which can be used to perform the calibration. The assigned values for MD CAL-KIT are based on replicate analyses on instruments, which have been whole blood, calibrated to values obtained by reference methods. The instruments use the manufacturer's recommended reagents.

REAGENTS
MD CAL-K1T contains human erythrocytes, mammalian leukocytes and platelets in a plasma-like fluid. MD CAL-KIT is for in vitro diagnostic use PRECAUTIONS WARNING POTENTIAL BIOHAZARDOUS MATERIAL MD CAL-KIT is intended solely for in vitro diagnostic use by trained qualified personnel. Human blood components used in MD CAL-KIT were found to be non-reactive for HbsAg and antibody to HIV-I, HIV-2, and HCV when tested with licensed reagents. No known test methods can provide complete assurance that products derived from human blood will not transmit infectious disease. Follow the same precautions as with patient samples when handling or disposing of tubes. Do not inject or consume by mouth. Do not pipette by mouth, use a mechanical pipetting device.

STORAGE AND STABILITY
Open vial stability is 7 days, provided the tubes are handled properly. The tubes must be mixed according to instructions before each sampling and should be stored, tightly capped, at 2-8 degrees C when not in use. See Instructions for Use section for detailed handling directions. Unopened tubes stored continuously at 2-8 degrees C are stable until the expiration date.

INDICATIONS OF DETERIORATION
Discoloration of the supernatant fluid may be caused by overheating or freezing during shipment or storage. Examine tubes for excess hemolysis. If deterioration is suspected, call Technical Service.

INSTRUCTIONS FOR USE
CAUTION: IF THESE INSTRUCTIONS ARE NOT CAREFULLY FOLLOWED, CALIBRATION ERRORS MAY RESULT

1. Perform instrument set up/start up procedures according to the Instrument Operation Manual. Before beginning the calibration procedure. Verify that instrument performance checks are acceptable and the reagent supply is adequate.

2. Mix and sample MD CAL-K1T as follows:
   a. Bring to ambient temperature by rolling the tube between the palms of the hands until the erythrocyte sediment is completely re-suspended.
   b. Mix by gently inverting tube 8-10 times.
   c. Sample the tube using the same technique as with a normal patient sample.
   d. After sampling:
      1. Manual sample handling - Carefully wipe the tube rim and closure with lint-free gauze. Replace the closure immediately.
      2. Automatic sample handling - Remove the tube from the sample loader when sampling is finished. Wipe the depression in the closure with lint-free gauze.

3. Prime the instrument by aspirating MD CAL-KIT one time. Discard the results.

4. Aspirate MD CAL-KIT 6 times. Review the data.
   a. Verify that the results are within the Coefficient of Variation (CV) precision claims published in the Operation Reference Manual.
   b. Verify that no trending (continual increase or decrease in values) has occurred.
   c. Do not continue with the next step until the two above criteria are met.
5. Compare the mean value for each parameter to the assigned value. If the WBC, RBC, HGB, MC'V and PLT mean values are within the Acceptable Range, calibration is not necessary.
6. If calibration is required, refer to the Operation Reference Manual.
7. Verify calibration by reanalyzing MD CAL-KIT 6 times. Mean values should be within the Acceptable Range (its best to use a previously unopened vial of MD CAL-KIT for this verification step.)
8. After completing the calibration and verification procedures, it is good laboratory practice to process a tri-level whole blood control product such as MD CAL-KIT though the instrument.

RESULTS
Refer to the assay table for the Assigned Value and Acceptable Range for each lot of MD CAL-KIT. Verify that the lot number on the assay table corresponds with the lot number on the calibrator tube in use.

PERFORMANCE CHARACTERISTICS
Laboratories may consider results acceptable when at least 95 percent of patient test results from an instrument calibrated to MD CAL-KIT are with-in 3 percent of values obtained on the patient sample using reference methods.

TECHNICAL ASSISTANCE - CUSTOMER SERVICE
Customers desiring technical assistance are encouraged to call our Customer Support Center at (800) 858-733 I. For additional information on DREW Scientific, Inc. hematology controls all our Customer Support Center at (800) 858-7331

REFERENCE METHODS
- WBC and RBC: A large volume, single-set dilution is made with calibrated glassware. Counts are performed on a single-aperture impedance cell counter and corrected for coincidence at all count levels.
- HGB: Hemaglobin value determined by pectrophotometric procedure described by NCCLS Standard H15-A2 and is traceable to ICSH/WHO International Haemiglogincyanide Standard.
- HCT: Packed cell volume (PCV) is measured by the microhematocrit procedure according to NCCLS Standard H7-A2. No correction is made for trapped plasma.
- MCV: MCV is calculated: PCVIRBC x 10
- PLT: Samples arc diluted in I percent ammonium oxalate and platelets are counted using a hemocytometer and phase contrast microscopy.

BIBLIOGRAPHY

1. National Committee for Clinical l.aboratory Standards. Reference and Selected Procedures for the Quantitative Determination of Hemaglobin in Blood-Second Edition; Approved Standard. NCCLS documents H 15-1\2. Villanova, PA 1994
2. National Committee for Clinical Laboratory Standards. Procedure for Determining Packed Cell Volume by the Microhematocrit Method: Approved Standard. NCCLS publication H7-A2.Villanova, PA 1993.

TRADEMARKS
MD CAL-KIT and MASCOT are trademarks of DREW Scientific, Inc.,Oxford. CT 06478