VetScan®
HEMATOLOGY

**HMT Normal Control Package Insert**
Part no. 700-9005
Lot No. AB1016N Expiration Date: **01/05/2017**

## Whole Blood Calibrator (Normal/Green Top)

The Abaxis Calibrator is intended for use with the VetScan® HMT Hematology System. The ranges for this calibrator have been established to confirm factory calibration. Refer to the next page when handling the calibrator.

**LOT # AB1016N**
**(Expires 01/05/2017)**

| **R & D Control** | **Normal/Green Cap** | | | |
|---|---|---|---|---|
| **Parameter** | **Assay** | **Gap** | **Range** | **Units** |
| WBC | 6.9 | 0.8 | 6.1 – 7.7 | K/ul |
| Lymphocyte | 35.8 | 5.0 | 30.8 – 40.8 | % |
| Mononuclear | 4.0 | 5.0 | 0.0 – 9.0 | % |
| Granulocyte | 60.3 | 5.0 | 55.3 – 65.3 | % |
| RBC | 4.85 | 0.20 | 4.65 – 5.05 | M/ul |
| Hemoglobin | 13.3 | 1.0 | 12.3 – 14.3 | g/dl |
| Hematocrit | 45.8 | 2.4 | 43.4 – 48.2 | % |
| MCV | 94.6 | 4.0 | 90.6 – 98.6 | fl |
| MCH | 27.4 | 2.8 | 24.6 – 30.2 | pg |
| MCHC | 29.0 | 3.0 | 26.0 – 32.0 | g/dl |
| Platelet | 187 | 68 | 119 – 255 | K/ul |
| MPV | 10.4 | 1.5 | 8.9 – 11.9 | fl |

# VetScan® HMT Package Insert

**INTENDED USE**
Whole Blood Calibrator is a control designed to monitor values on HMT, HMII and HM2 analyzers.

**SUMMARY AND PRINCIPLE**
It is an established laboratory practice to use a stable control to monitor the performance of diagnostic tests. This control is composed of stable materials that provide a means of monitoring the performance of hematology cell counters. It is sampled in the same manner as a patient specimen.

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

**PRECAUTIONS**
Whole Blood Calibrator is intended for ***in vitro*** **diagnostic use** only by trained personnel.

**WARNING**
**POTENTIAL BIOHAZARDOUS MATERIAL:** This product contains human-sourced and/or potentially infectious components. For specifics please refer to the REAGENT section of this package insert. Components from human donors used in preparation of this product were tested by FDA approved methods for the presence of the antibodies to Human Immunodeficiency Virus (HIV-1 and HIV-2) and Hepatitis C Virus (HCV), as well as for Hepatitis B Virus surface antigen and found to be negative. No Known method can offer complete assurance that products derived from human sources or containing inactivated microorganism will not transmit infection. When handling or disposing of product, follow precautions for patient specimens as specified in the OSHA Blood borne Pathogen Rule (OSHA 29 CFR part 1910.1030) or other equivalent biosafety procedure.

**STABILITY AND STORAGE**
Store Whole Blood Calibrator upright at 2-8$^{o}$ C (35-46$^{o}$ F) when not in use. **Protect vials from overheating and freezing.** Unopened vials are stable through the expiration date. Opened vials are stable for 14 days, provided they are handled properly.

**INDICATION 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 doesn't indicate deterioration. Other discoloration, very dark red supernatant or unacceptable results may indicate deterioration. **Do not use the product if deterioration is suspected.**

**INSTRUCTION FOR USE**
1. Remove tubes/vials from the refrigerator and allow warming to room temperature (15 to 30°C or 59 to 86°F) for 15 minutes before mixing.
2. Hold the tube/vial horizontally between the palms of the hands for mixing. **DO NOT PRE-MIX ON A MECHANICAL MIXER.**
   a. Roll the tube/vial back and forth for 20-30 seconds; occasionally invert 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 sampling.
3. Analyze the sample as instructed in the Quality Control section of the Operator's Manual for your instrument.
4. After Sampling:
   a. If tube/vial has been open for sampling, clean residual material from the cap and tube rim with a lint-free tissue. Replace the cap tightly.
   b. Return tubes/vials to refrigerator within 30 minutes of use.

**EXPECTED RESULTS**
Verify that the lot number on the vial matches the lot number on the table of assay values. Assay values are determined on well-maintained, properly calibrated instruments using the instruments manufacturer's recommended reagents. Reagent differences, maintenance, operating technique, and calibration may contribute to the inter-laboratory variation.

**PERFORMANCE CHARACTERISTICS**
Assigned values are presented as a Mean and Range. The Mean is derived from replicate testing on VetScan Hematology instruments operated and maintained according to Abaxis instructions. The Range is an estimate of variation between laboratories and also takes into account inherent imprecision of the method and expected biological variability of the control material. Assay values on a new lot of control should be confirmed before the new lot is put into routine use. Test the new lot when the instrument is in good working order and quality control results on the old lot are acceptable. The laboratory's recovered mean should be within the assay range. For greater control sensitivity each laboratory should establish its own mean and acceptable range and periodically reevaluate the mean. The laboratory range may include values outside of the assay range. The used may establish assay values not listed on the assay sheet, if the control is suitable for the method.

**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/vial.

**TECHNICAL ASSISTANCE AND CUSTOMER SERVICE**
For assistance in resolving control recovery problems, for additional information, or to place an order please call our Technical Service or Customer Service Department at 800-822-294.