Myt-CAL VET

HEMATOLOGY CALIBRATOR

CALIBRATOR

MYTCAL2-VET

LOT **PLUS0724**

2024-08-05

Calibration Values for Mythic 18 VET II Generation Reagents

Parameter	Assigned Value	Acceptable Range
WBC K/µL	9.1	8.9 - 9.3
RBC M/µL	4.43	4.33 - 4.53
HGB g/dL	13.1	12.9 - 13.3
HCT %	37.2	36.2 - 38.2
PLT K/µL	240	228 - 252

INTENDED USE

Myt-CAL VET is designed for use in the calibration of Veterinary Auto Hematology Analyzers.

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 Veterinary Auto Hematology Analyzers.

Calibrator values for **Myt-CAL VET** 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

Myt-CAL VET is a reagent composed of human erythrocytes, mammalian leukocytes and mammalian platelets suspended in a plasma-like fluid with preservatives.

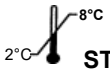
Warning

H315 Causes skin irritation.
H319 Causes serious eye irritation.
P280 Wear protective gloves, protective clothing, eye protection or face protection.
P302 + P352 IF ON SKIN: Wash with plenty of soap and water.
P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

POTENTIAL BIOHAZARDOUS MATERIAL.

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.



STABILITY AND STORAGE

Store **Myt-CAL VET** 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:
   a) Automatic Sample Handling: Remove the tube/vial from the sample handler immediately after sampling.
   b) Manual Sample Handling: 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 Acceptable Range, calibration is optional.
   b) If the difference is not within the Acceptable Range, calibration may be needed.
4. Acceptable Ranges given on the assay sheet are intended as guidelines, but not absolute limits, for evaluating instrument calibration. Acceptable calibration should be established by each laboratory.

C. 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”.

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 NCCLS 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 NCCLS Standard H7-A3. No correction is made for trapped plasma.
5. **PLT:** A series of 1:125 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/vial.

TECHNICAL ASSISTANCE AND CUSTOMER SERVICE

For assistance in resolving control recovery problems, please use contact form available on our website.
For additional information on Orphée hematology controls and calibrators, or to place an order, call your local Orphée representative Customer Service or contact the Orphée’s Customer Service. Contact form is available on our website.

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