



HM5 Low Control	Part No. 770-9028	Lot. No. 91641
HM5 Normal Control	Part No. 770-9029	Lot. No. 91672
HM5 High Control	Part No. 770-9030	Lot. No. 91643

Expiration Date: 4/24/2017

HM5 Control Values for Quality Control

If you use these controls to perform quality control, please refer to the assay and gap values in the table below.

Expires:	Low: Lot #91641		Normal: Lot #91672		High: Lot #91643		Units
	4/24/2017		4/24/2017		4/24/2017		
Parameter	Assay	Gap (±)	Assay	Gap (±)	Assay	Gap (±)	
WBC	3.8	± 0.4	8.0	± 1.0	19.5	± 2.5	K/μl
RBC	2.4	± 0.20	4.20	± 0.30	4.77	± 0.40	M/μl
HGB	5.3	± 0.5	12.0	± 0.7	15.6	± 0.8	g/dl
HCT	18.5	± 2.5	37.4	± 3.0	45.8	± 4.0	%
MCV	77	±6.0	89	± 7.0	96	± 7.0	fl
MCH	22.1	± 2.6	28.6	± 3.0	32.7	± 3.0	pg
MCHC	28.6	± 3.5	32.1	± 3.5	34.1	± 3.0	g/dl
PLT	90	± 25	267	± 40	594	± 70	K/μl
PCT	0.10	± 0.06	0.32	± 0.12	0.71	± 0.20	%
MPV	11.4	± 3.0	12.1	± 4.0	12	± 4.0	fl
PDW-CV	36.3	± 12.0	33.8	± 6.0	34.9	± 4.0	%
RDW-CV	19.5	± 5.0	16.7	± 5.0	15.7	± 5.0	%
LYM	1.3	± 0.5	3.0	± 0.6	11.5	± 1.5	K/μl
MON	0.4	± 0.4	0.5	± 0.5	0.8	± 0.8	K/μl
NEU	2.1	± 0.9	4.5	± 1.1	7.2	± 2.5	K/μl
EOS	2.1	± 0.4	4.4	± 1.0	6.6	± 1.3	K/μl

Scan the barcode below to enter the control values above into the touchscreen/color HM5. For more information, contact [Abaxis](http://Abaxis.com).

FOR CALIBRATION
Normal Level Control
LOT #91672

Please use the assay table below for instrument calibration (when the default choice MCV & MPV calibration is selected).

Control Parameter	Assay	Units
RBC	4.20	M/μl
MCV	89	fl
RDWc	16.7	%
PLT	267	K/μl
MPV	12.1	fl
HGB	12.0	g/dl
WBC	8.0	K/μl
EOS	4.4	K/μl



VetScan HM5 Hematology Controls

INTENDED USE

The VetScan® HM5 controls are intended for use with the VetScan HM5 and color HM5 Hematology Systems. The HM5 normal control serves as both as an instrument calibrator to confirm factory calibration and as quality control material. Refer to the next page for instructions on handling the calibrator.

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

HM5 Low, Normal or High controls are in vitro diagnostic reagents composed of human erythrocytes, simulated leukocytes and mammalian platelets suspended in a plasma-like fluid with preservatives.

PRECAUTIONS

HM5 controls are 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 by the OSHA Blood-borne Pathogen Rule (OSHA 29 CFR 1910.1030) or equivalent biosafety procedure.

STABILITY AND STORAGE

Store HM5 controls upright at 2-8° C (35-46° 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 or more, provided they are stored and 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 between the thumb and forefinger to mix. DO NOT PRE-MIX ON A MECHANICAL MIXER.
- 2a Slowly invert the tube/vial back and forth for 20-30 seconds; Mix thoroughly, but do not shake.
- 2b Continue to mix in this manner until the red cells are completely suspended. Tubes/vials stored for a long time may require extra mixing.
- 2c Gently invert the tube/vial 8-10 times immediately before sampling.
- 3 Analyze the sample as instructed in the Calibration or Quality Control section of the Operator's Manual for your
- 4 After Sampling:
 - 4a 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.
 - 4b 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 HM5 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 Support or Customer Support Departments at 800-822-2947.