



HM5 Control Package Insert

HM5 Low Control	REF 10023313	Lot. No. 00000
HM5 Normal Control	REF 10023314	Lot. No. 92154
HM5 High Control	REF 10023315	Lot. No. 00000

Expiration Date: 1/4/2022

HM5 Control Values for Quality Control

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

Expires:	Low: Lot #00000		Normal: Lot #92154		High: Lot #00000		Units
	1/4/2022		1/4/2022		1/4/2022		
Parameter	Target	Range (±)	Target	Range (±)	Target	Range (±)	
WBC	0.0	± 0.0	8.0	± 1.0	0.0	± 0.0	K/μl
RBC	0.00	± 0.00	4.66	± 0.30	0.00	± 0.00	M/μl
HGB	0.0	± 0.0	10.9	± 0.7	0.0	± 0.0	g/dl
HCT	0.0	± 0.0	38.2	± 3.0	0.0	± 0.0	%
MCV	0	± 0.0	82	± 7.0	0	± 0.0	fl
MCH	0.0	± 0.0	23.4	± 3.0	0.0	± 0.0	pg
MCHC	0.0	± 0.0	28.5	± 3.5	0.0	± 0.0	g/dl
PLT	0	± 0	222	± 40	0	± 0	K/μl
PCT	0.00	± 0.00	0.24	± 0.12	0.00	± 0.00	%
MPV	0.0	± 0.0	10.7	± 4.0	0.0	± 0.0	fl
PDW-CV	0.0	± 0.0	34.6	± 6.0	0.0	± 0.0	%
RDW-CV	0.0	± 0.0	20.0	± 5.0	0.0	± 0.0	%
LYM	0.0	± 0.0	3.5	± 0.6	0.0	± 0.0	K/μl
MON	0.0	± 0.0	0.5	± 0.5	0.0	± 0.0	K/μl
NEU	0.0	± 0.0	4.0	± 1.1	0.0	± 0.0	K/μl
EOS	0.0	± 0.0	4.5	± 1.0	0.0	± 0.0	K/μl

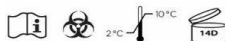
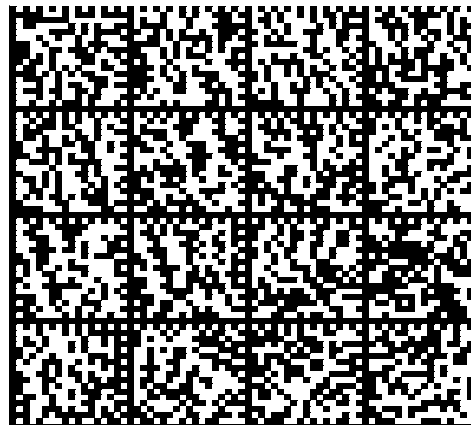
Scan the barcode below to enter the control values above into the touchscreen/color HM5. For more information, contact Zoetis.

FOR CALIBRATION Normal Level Control

LOT #92154

Enter the target values below to calibrate either the HM5 or color HM5 instruments.

Control Parameter	Target	Units
RBC	4.66	M/μl
MCV	82	fl
RDWc	20.0	%
PLT	222	K/μl
MPV	10.7	fl
HGB	10.9	g/dl
WBC	8.0	K/μl
EOS	4.5	K/μl



FOR VETERINARY USE ONLY

Clinical Diagnostic Solutions, Inc.
1800 NW 65 Avenue, Plantation,
FL 33313 USA

Zoetis Inc.
333 Portage Street,
Kalamazoo, MI, 49007
USA

Zoetis Belgium S.A.
Rue Loid Burmat 1
1348 Louvain-La-Neuve
Belgium

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 *veterinary use only* reagents composed of human erythrocytes, simulated leukocytes and mammalian platelets suspended in a plasma-like fluid with preservatives.

PRECAUTIONS

HM5 controls are intended for *veterinary 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 REAGENTS 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 2-10° C (35-50° 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.

INSTRUCTIONS 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 instrument.
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 control values. Control 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

Control values are presented as a Target and Range. The Target is derived from replicate testing on VetScan HM5 instruments operated and maintained according to Zoetis 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. Target 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 results should be within the control range. For greater control sensitivity each laboratory should establish its own target and acceptable range and periodically reevaluate the target. The laboratory range may include values outside of the assay range. The user may establish target values not listed on the assay sheet, if the control is suitable for the method.









LIMITATIONS

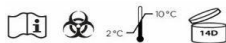
The performance of this product is assured only if it is properly stored and used as described in this insert. Incomplete mixing of a tube/vial prior to use invalidates both the sample withdrawn and any remaining material in the tube/vial.

TECHNICAL ASSISTANCE AND CUSTOMER SERVICE

For assistance in resolving control problems, for additional information, or to place an order please call our Technical Support or Customer Support Departments at 800-822-2947.

SYMBOLS

	Biological risk
	Consult instructions for use
	Lot number of control
	Use-by-date
	Expiration date of product once opened, 14 days
	Temperature limit
	Manufacturer
	Distributor



FOR VETERINARY USE ONLY

Clinical Diagnostic Solutions, Inc.
1800 NW 65 Avenue, Plantation,
FL 33313 USA

Zoetis Inc.
333 Portage Street,
Kalamazoo, MI, 49007
USA

Zoetis Belgium S.A.
Rue Laid Burnat 1
1348 Louvain-La-Neuve
Belgium