Instructions for Hematology Control

Product Name

Hematology Control

Packaging

Model	Specifications
DM-6D	3 mL×1 (H)
	3 mL×2 (H)
	3 mL×3 (H)
	3 mL×1 (N)
	3 mL×2 (N)
	3 mL×3 (N)
	3 mL×1 (L)
	3 mL×2 (L)
	3 mL×3 (L)
	3 mL (H) ×1+3 mL (N) ×1 +3 mL (L) ×1

Intended Use

It is used in the quality control of auto hematology analyzers DH-600, DH-602, DH-605, DH-610, DH-612, DH-615, DH-800[H1], DH-800[H2], DH-800[H3], DH-800[H4], DH-800[H5], DH-800[H6], DH-800[H7], DH-800[H8], DH-800[T1]CRP, DH-800[T2]CRP, DH-800[T3]CRP, DH-800[T4]CRP, DH-800[T5]CRP, DH-800[T6]CRP, DH-800[T7]CRP, DH-800[T8]CRP, DH-800[T1]CS, DH-800[T2]CS, DH-800[T3]CS, DH-800[T4]CS, DH-800[T5]CS, DH-800[T6]CS, DH-800[T7]CS, DH-800[T8]CS manufactured by Shenzhen Dymind Biotechnology Co., Ltd to monitor and evaluate the repeatability of test results of the analyzer.

Principle

The control contains a variety of small particles of animal origin, which have the properties similar to the leukocytes, erythrocytes and platelets in human blood. These particles can accurately simulate human blood and monitor the status of the analyzer when tested on the analyzer.

Components

The control is composed of simulated leukocytes, simulated erythrocytes, simulated platelets, depositary agent and preservatives.

Note: The reference value of the control may vary from batch to batch, and the reference value table of the control for the corresponding batch is attached.

Storage and Stability

- The product can be stably stored for 90 days at 2°C~8°C.
- After opening, the product is stable for 14 days if stored upright at 2°C~8°C.
- Date of manufacture and expiration: see product label.

Note: Protect the product from violent vibration and freezing, or the test results may be affected.

Applicable Analyzers

The product is applicable to the following auto hematology analyzers produced by Dymind: DH-600, DH-602, DH-605, DH-610, DH-612, DH-615, DH-800[H1], DH-800[H2], DH-800[H3], DH-800[H4], DH-800[H5], DH-800[H6], DH-800[H7], DH-800[H8], DH-800[T1]CRP, DH-800[T2]CRP, DH-800[T3]CRP, DH-800[T4]CRP, DH-800[T5]CRP, DH-800[T6]CRP, DH-800[T7]CRP, DH-800[T8]CRP, DH-800[T1]CS, DH-800[T2]CS, DH-800[T3]CS, DH-800[T4]CS, DH-800[T5]CS, DH-800[T6]CS, DH-800[T7]CS and DH-800[T8]CS.

Test Method

1. Take the control out of the refrigerator and place it at room temperature (15°C~32°C) for 15 minutes to allow it to equilibrate to room temperature.
2. Mix the control. (Do not use the mechanical mixer)
   a. Hold the control horizontally between two palms, rotate the control horizontally between two palms for 20 to 30 seconds, and turn it up and down several times during this period for thoroughly mixing. Do not shake.
   b. Repeat step a until RBCs are completely suspended.
   Note: The control should be mixed thoroughly again before use if it has been placed for a long time.
   c. Gently turn the control up and down 8 to 10 times before the test.
3. Refer to the hematology analyzer operator's manual for QC procedure.
4. After the control is opened and used, wipe off the residue on the thread of the bottle and the cap with clean soft paper, tighten the cap, and put it back to the refrigerator. Store the control upright.

Interpretation of Test Results

- The reference values are determined on the analyzer that is well-maintained, properly calibrated, and uses original reagents. Reagent differences, maintenance, operating techniques and calibration may result in differences in test results.
- The parameters and performance indicators of the control are only valid for the applicable devices.
- The reference values of a new lot of control should be confirmed before the new lot is put into routine use. Test the new lot when the device is in good working condition and the QC results of the old lot are within the acceptable range. The average of repeated tests should be within the reference range.
- If the results are abnormal, repeat the control test or test a new lot of control. If the results still do not meet the requirements, analyze the source of problem to solve the problem.
- Each laboratory should establish its own average and reference range, and periodically re-evaluate the average. The laboratory range can include values outside the reference range. You can set the reference value without following the reference value table if the QC is suitable for the method.

Limitations of the Test Method

- The value of this product is batch-specific, and there may be differences in the value of controls between different batches.
- The control is only applicable to the designated test system.
- The control cannot be used as a standard substance.

Performance Specifications

The within-bottle homogeneity of the control should meet the requirements of the table below.

Parameter	Concentration Level	CV/%
WBC	L	≤3.0
	N	≤2.5
	H	≤2.5
RBC	L	≤2.0
	N	≤1.5
	H	≤1.5
HGB	L	≤2.0
	N	≤1.0
	H	≤1.0
HCT	L	≤2.0
	N	≤1.5
	H	≤1.5
MCV	L	≤1.0
	N	≤1.0
	H	≤1.0
PLT	L	≤8.0
	N	≤4.0
	H	≤4.0

The between-bottle homogeneity of the control should meet the requirements of the table below.

Parameter	CV/%
WBC	≤2.5
RBC	≤1.0
HGB	≤1.0
HCT	≤1.0
MCV	≤1.0
PLT	≤4.0

Test a control during storage and opening period on an applicable instrument. The acceptable deviation of results should meet the requirements of the table below.

Parameter	Unit	L	N	H
WBC	$\times10^9$/L	±1.20	±1.80	±3.00
Neu#	$\times10^9$/L	±0.40	±0.80	±2.00
Lym#	$\times10^9$/L	±0.40	±0.70	±1.80
Mon#	$\times10^9$/L	±0.40	±0.50	±0.80
Eos#	$\times10^9$/L	±0.40	±0.70	±1.60
Bas#	$\times10^9$/L	±0.40	±0.70	±1.60
IG#	$\times10^9$/L	±0.50	±1.00	±2.50
Neu%	%	±12.0	±12.0	±12.0
Lym%	%	±10.0	±10.0	±10.0
Mon%	%	±8.0	±8.0	±8.0
Eos%	%	±10.0	±10.0	±10.0
Bas%	%	±10.0	±10.0	±10.0
IG%	%	±10.0	±10.0	±10.0
NRBC#	$\times10^9$/L	±1.50	±1.50	±1.50
NRBC%	%	±10.0	±10.0	±10.0
RBC	$\times10^{12}$/L	±0.20	±0.30	±0.50
HGB	g/L	±4	±6	±8
HCT	%	±2.0	±2.5	±3.0
MCV	fL	±5.0	±5.0	±5.0
MCH	pg	±2.5	±2.5	±2.5
MCHC	g/L	±30	±30	±30
RDW-CV	%	±5.0	±5.0	±6.0
RDW-SD	fL	±10.0	±10.0	±12.0
PLT	$\times10^9$/L	±20	±45	±65
MPV	fL	±3.0	±3.0	±3.0
PDW	fL	±5.0	±5.0	±5.0
PCT	%	±0.050	±0.100	±0.200
IPF	%	±15.0	±15.0	±15.0
P-LCR	%	±20.0	±20.0	±20.0
P-LCC	$\times10^9$/L	±10	±30	±50
WBC-D	$\times10^9$/L	±1.20	±1.80	±3.00
RBC-O	$\times10^{12}$/L	±0.30	±0.50	±0.60
PLT-O	$\times10^9$/L	±40	±65	±85

Precautions

- The control must be used by qualified personnel or trained clinical staff.
- Read the instructions carefully before use to make sure that the lot number on the product bottle is consistent with the lot number on the reference value table.
- Mix the control thoroughly according to the instructions before use. Incorrect mixing method will cause the product that has been used and the remaining product in the bottle to be invalid.
- Use the control before the expiration date. Do not use expired control.
- Do not use deteriorated product. When the control is not mixed, the surface of the liquid may be cloudy, reddish or dark red; after mixing, it will be a red or dark red liquid, which looks similar to fresh whole blood. If there are other colors or its status changes, it means that the control has deteriorated.
- The product is for in vitro diagnostics only. Do not ingest, avoid contact with skin and eyes. Once in contact, rinse immediately with plenty of water. If swallowed by mistake or splashed into your eyes, please seek medical attention.
- POTENTIAL BIOHAZARDOUS MATERIAL. The control contains materials of animal origin. It has passed the reagent kit test approved by National Medical Products Administration before production, and the test results of HBsAg, HIV-1/HIV-2 antibody, HCV antibody and Treponema pallidum antibody (TP) are all negative. However, the current detection level cannot ensure the detection of all pathogens, so the product still has potential biological hazards. Wear standard laboratory protective clothing and gloves when using the control, and abide by the laboratory safety operation regulations.
- Please dispose of waste and remaining reagents in accordance with local regulations and relevant environmental protection requirements.
- Any serious incident that occurs in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.

Interpretation of Symbols

	Consult instructions for use or consult electronic instructions for use	LOT	Batch code
IVD	In Vitro diagnostic medical device		Date of Manufacture
	Biological risks		Temperature limit
	Use-by date	CONTROL	Control
CE	CE MARKING OF CONFORMITY		Manufacturer
EC REP	Authorized representative in the European Community/European Union		

Contact Information

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Release Date

2022-09-30

Date of Manufacture

See product label

IVD CE