

Lyophilized Control Hemolysate

HEMOGLOBIN CONTROL SET
(Assayed Control Hemolysate)

3 levels

Lyophilized control hemolysate for the use in tests for the quantitative and qualitative in vitro determination of total hemoglobin in blood with the cyanmethemoglobin hemoglobin procedure.

REF	Cont.		
Y04706	6 x 2 ml	2 x 2 ml L1 2 x 2 ml L2 2 x 2 ml L3	finished kit
Y04706SV	3 x 2 ml	1 x 2 ml L1 1 x 2 ml L2 1 x 2 ml L3	labelled vials (OEM)
Y04706VSV	3 x 2 ml	1 x 2 ml L1 1 x 2 ml L2 1 x 2 ml L3	unlabelled vials (OEM)

COMPOSITION

Hemoglobin prepared from human erythrocytes. Preservatives added. Stabilizers are added to maintain haemoglobin in the reduced state providing complete control of the cyanmethemoglobin test. The lyophilized haemoglobin controls provide multiple levels of hemoglobin.

CONTROL PREPARATION

1. Open the vial very carefully, avoiding any loss of the lyophilized material.
2. Add exactly 2 ml of deionized water (inaccurate reconstitution of the control and error in assay technique can cause erroneous results).
3. Close the vial carefully and allow the controls to stand for 15 minutes with occasional gentle mixing, avoiding the formation of foam. Do not shake!
4. The controls should be assayed in the same manner as unknown blood specimens.

CONTROL STABILITY AND STORAGE

Storage: at 2 – 8°C
 Stability: until date of expiration date if sealed tightly.
 Stability after reconstitution:
 90 days at 2-8°C
CLOSE IMMEDIATELY AFTER USE.
PROTECT FROM LIGHT AND HEAT.
 The presence of obvious turbidity after reaction with cyanmethemoglobin reagent would indicate deterioration, and the product should not be used.

LOT SPECIFIC ASSAY DATA

Lot: 702502-025 Exp: 2009/02	Hemoglobin Total [g/dl] manual	Hemoglobin Total [g/dl] automated (Cobas Mira)
Level 1:	8.4 (8.0 – 8.8)	8.7 (8.3 – 9.1)
Level 2:	12.0 (11.4 – 12.6)	12.4 (11.8 – 13.0)
Level 3:	15.3 (14.6 – 16.0)	15.6 (14.8 – 16.4)

EXPECTED VALUES

Mean value: the average value obtained by assaying representative samples of the entire lot using the cyanmethemoglobin hemoglobin procedure.
 Expected range: the acceptable limits to be used as a guide in determining the accuracy of the assay procedure. The assay results for the controls should fall within the stated expected range.
 Among factors that might cause inaccurate results are improper pipetting, inadequate mixing and poorly calibrated instruments.

WARNINGS AND PRECAUTIONS

1. This product is for in vitro diagnostic use only.
2. Handle with the same precautions used for human blood samples.
3. The human blood used in this product has been tested and found to be non-reactive for hepatitis B surface antigen, hepatitis C antigen, and HIV antibody.
4. Refer to material safety data sheets for any updated risk, hazard or safety information.
5. Do not pipette by mouth. Avoid contact with skin and mucous membranes.

WASTE MANAGEMENT

Please refer to local legal requirements.

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