

Lyophilized Control Blood

**G6PDH Control Set
(Assayed Control Blood)**

3 levels

Lyophilized control blood for the use in tests for the quantitative and qualitative in vitro determination of glucose-6-phosphate dehydrogenase (G6PDH) in blood.

REF	Cont.		
Y04560	6 x 0,5 ml	2 x 0.5 ml L1 2 x 0.5 ml L2 2 x 0.5 ml L3	finished kit
Y04560SV	6 x 0,5 ml	2 x 0.5 ml L1 2 x 0.5 ml L2 2 x 0.5 ml L3	labelled vials (OEM)
Y04560VSV	6 x 0,5 ml	2 x 0.5 ml L1 2 x 0.5 ml L2 2 x 0.5 ml L3	unlabelled vials (OEM)

COMPOSITION

Lyophilized, entirely human blood based control. The controls contain 10-12 g/dl Hemoglobin. The controls show 3 levels of G6PDH – normal, intermediate (appr. 50% of normal) and very low G6PDH activity.

CONTROL PREPARATION

1. Open the vial very carefully, avoiding any loss of the lyophilized material.
2. Add exactly 0.5 ml of deionized water (inaccurate reconstitution of the control and error in assay technique can cause erroneous results).
3. Close the vial carefully and gently swirl to dissolve.
4. Allow the controls stand 15 minutes.
5. Invert gently and swirl to assure homogeneity of the controls, avoiding the formation of foam. Do not shake!
6. Let the controls stand at least 10 minutes. Swirl gently just prior to each use. Avoid foaming. Do not shake.
7. Treat the controls as you would a patient sample and test each level in accordance with the requirement of the test method.

CONTROL STABILITY AND STORAGE

Storage: at 2 – 8°C
 Stability: until date of expiration date if sealed tightly.
 Stability after reconstitution:
 7 days at 2-8°C
**CLOSE IMMEDIATELY AFTER USE.
 PROTECT FROM LIGHT AND HEAT.**
 Do not use the product if there is visible evidence of microbial growth in the vial.
 Improper handling and/or storage of the controls can affect results.

LOT SPECIFIC ASSAY DATA

Lot: 711602 Exp: 2008/12	G6PDH [U/L]	Hemoglob. Total [g/dl]	G6PDH [U/gHb]
Normal:	1244 (871-1617)	13.7	9.1 (6.4-11.8)
Intermediate:	477 (334-620)	12.0	3.7 (2.6-4.8)
Deficient:	97 (34-160)	12.3	0.79 (0.28-1.3)

EXPECTED VALUES

The G6PDH values were determined by repetitive assays of the Dialab method. Values listed are targets only. Measurements using other reagents and instrument systems may give different results. It is recommended that each laboratory should establish its own target value and acceptable range.

WARNINGS AND PRECAUTIONS

1. This product is for in vitro diagnostic use only.
2. The controls were tested at the donor level and found to be non-reactive for Hepatitis B and C surface antigen and HIV by approved methods. No known test method can assure that a product derived from human blood does not contain Hepatitis or HIV virus. Therefore all human serum products and patient specimens should be handled in the same manner as an infectious agent.
3. Refer to material safety data sheets for any updated risk, hazard or safety information.
4. Do not pipette by mouth. Avoid contact with skin and mucous membranes.

WASTE MANAGEMENT

Please refer to local legal requirements.



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