

TruLab G6PDH

Order Information

Cat. No. 1 7900 99 10 045 Kit size 3 x 0.5 mL (3 levels)

Intended Use

Controls for quantitative in-vitro determination of glucose-6-phosphate dehydrogenase (G6PDH) in erythrocytes on photometric systems.

Description

TruLab G6PDH is a set of three lyophilized controls (three levels) of human origin (stabilized human blood).

Storage

The unopened vials must be stored at 2 – 8°C.

Stability

Unopened: Until the end of the indicated month of expiry

Reconstituted: 7 days at 2 – 8°C
 20 days at –20°C

After reconstitution freeze only once.

Proper storage and handling of this product must be observed.

Warnings and Precautions

1. Each individual blood donation used for production of TruLab G6PDH was found to be non-reactive when tested with approved methods for HBsAg, anti HIV 1+2 and anti-HCV. As there is no possibility to exclude definitely that products derived from human blood transmit infectious agents, it is recommended to handle the control with the same precautions used for patient specimens.
2. Please refer to the safety data sheets and take the necessary precautions for the use of calibrators and controls.
3. For professional use only.

Waste Management

Refer to local legal requirements.

Preparation

The lyophilisate is vacuum sealed; therefore the vial should be opened very carefully to avoid loss of dried material. For reconstitution add exactly 0.5 mL of distilled water. Close the vial carefully and allow the control to stand for 10 minutes swirling occasionally. Avoid foaming! Do not shake!

Allow the control to reach room temperature before use. Close immediately after handling.

Materials Required

General laboratory equipment

Procedure

Please refer to the reagent package insert for instructions for use.

Assay Values

Assay values may vary with different reagents and methodologies used. The assay values listed below are specific for this lot number of control only.

Each laboratory should establish corrective action in case of deviations in control recovery.

Literature

1. Röhle G, Siekmann L. Quality assurance of quantitative determination. In: Thomas L, editor. Clinical laboratory diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 1393-1401.
2. Biosafety in Microbiological and Biomedical Laboratories, US Department of Health and Human Services, Washington 2009



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	Lot No.	Expiry Date	Assay Value	Range
TruLab G6PDH Level 1	DY007T	2024-11-30	380 U/L	266 – 494 U/L
TruLab G6PDH Level 2			770 U/L	539 – 1001 U/L
TruLab G6PDH Level 3			1930 U/L	1351 – 2509 U/L