



G6PD 3Level Controls Set

IVD For In-Vitro diagnostic and professional use only



2°C / 8°C
Store at 2-8°C

INTENDED USE

This control is designed for use in the quality control of procedures which determine G-6-PD quantitatively or qualitatively. This control serves to verify procedure reliability when assayed with test samples.

INTRODUCTION

Glucose-6-phosphate dehydrogenase (G6PD or G6PDH) is a cytosolic enzyme that participates in the pentose phosphate pathway, a metabolic pathway that supplies reducing energy to cells (such as erythrocytes) by maintaining the level of the co-enzyme nicotinamide adenine dinucleotide phosphate (NADPH). The NADPH in turn maintains the level of glutathione in these cells which helps protect the red blood cells against oxidative damage from compounds like hydrogen peroxide. Clinically, an X-linked genetic deficiency of G6PD predisposes a person to non-immune hemolytic anemia.

MATERIALS PROVIDED

- G6PD Normal Level Control.
- G6PD Intermediate Level Control.
- G6PD Deficient Level Control.

PRECAUTION

- Controls should be treated in the exact manner as unknown blood sample.
- For in-vitro diagnostic use only. For professional use only.
- Do not use the control if packaging is damaged and discard the contents immediately.

- Do not mix controls of different lots. Do not use expired controls.
- Follow good laboratory practice and safety guidelines. Wear lab coats, disposable latex gloves and protective glasses where necessary.
- Disposal of these reagents should be accompanied by copious flushing with water to avoid accumulation of explosive salts in plumbing systems.
- Chemicals and prepared or used reagents have to be treated as hazardous waste according to national biohazard and safety guidelines or regulations.
- This product is a human red cell hemolysate. Source materials have been found negative for HBsAg, CMV, HIV-1 and HIV-2. Since no test method can offer complete assurance that infectious agents are absent, this product should be handled as a “potentially infectious material”.

PREPARATION

Each vial should be reconstituted with 0.5 ml of distilled water. Allow to stand for 5 minutes. Then swirl gently till complete dissolution.

STORAGE AND STABILITY

- Vials stored at 2-8°C are stable till the Expiry date on the label.
- After reconstitution, controls are stable for 1 week at (2-8°C) or 3 weeks frozen (-20°C).
- Do not freeze-thaw more than one time.
- If turbidity develops, the products should be discarded.

PROCEDURE

















Follow G6PD kit procedure.

RESULT

Refer to the attached Data Sheet.

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	Catalogue Number		Temperature limit
	<i>In Vitro</i> diagnostic medical device		Caution
	Contains sufficient for <n> tests and Relative size		Consult instructions for use (IFU)
	Batch code		Manufacturer
	Fragile, handle with care		Use-by date
	Manufacturer fax number		Do not use if package is damaged
	Manufacturer telephone number		Date of Manufacture
	Keep away from sunlight		Keep dry