Size : 137 x 218 mm

Seroquant G6PD

Lyophilized Control set for Neonatal G6PD assay

INTENDED USE

G6PD Controls are intended for use as quality control materials in the routine monitoring of precision and accuracy of Neonatal G6PD immunoassay.

SUMMARY

G6PD is an enzyme, and G6PD deficiency is an inherited genetic disorder where red blood cells lack sufficient levels of the enzyme glucose-6-phosphate dehydrogenase. This deficiency can cause red blood cells to break down prematurely when exposed to certain triggers like certain medications, infections, or fava beans, a condition called hemolysis. Symptoms, which often don't appear unless triggered, include jaundice, dark urine, fatigue, and shortness of breath, which are indicative of hemolytic anemia. Treatment involves avoiding triggers and sometimes managing complications with interventions like blood transfusions.

Newborn Screening for G6PD deficiency, a test to detect glucose-6-phosphate dehydrogenase deficiency in newborns before symptoms appear. The screening helps identify the condition early that allows for prompt management, which involves preventing exposure to triggers, and can effectively control severe jaundice and prevent potential long-term complications such as brain damage in newborns if left untreated. The screening involves analysing a newborn's blood sample for low levels of the G6PD enzyme.

PRODUCT DESCRIPTION

Seroquant G6PD controls are prepared in a synthetic buffered matrix. Each control is a lyophilised, buffer-based material containing G6PD at normal and deficient concentration levels.

PRINCIPLE

Quality control materials are analyzed along with patient samples to verify the reliability of assay performance. Results should fall within the assigned range for the respective control level. Deviations may indicate reagent deterioration, calibration errors, or instrument malfunction.

PRESENTATION

REF	547010201
Pack Size	2x0.1 ml
Control Level-I	0.1 ml
Control Level-II	0.1 ml
PACKAGE INSERT	01 No.

REAGENTS PROVIDED

Component	Description	Quantity
G6PD normal control	Lyophilized, buffer-based control.	1 vial
G6PD deficient control	Lyophilized, buffer-based control containing G6PD at a low concentration	1 vial

MATERIAL REQUIRED BUT NOT PROVIDED

- Distilled or deionized water
- Calibrated pipettes and tips
- G6PD assay reagents and analyzer

PROCEDURE

1. Remove the vial from 2–8 °C and allow it to reach room temperature.
2. Add 0.1 ml of distilled or deionized water to the vial.
3. Gently swirl (do not shake) until completely dissolved.
4. Allow to stand for 5 minutes before use.
5. Mix gently before each use.
6. Run the controls in the same manner as patient samples according to the instructions of the G6PD assay kit.

Colour	C	M	Y	K
Black	0	0	0	100
Green	100	20	100	10

Size : 137 x 218 mm

STORAGE AND STABILITY

Condition	Stability
Unopened (lyophilised)	Stable until expiry when stored at 2–8 °C.
After reconstitution	Stable for 2 days at 2–8 °C.

PRECAUTIONS AND WARNINGS

- For in vitro diagnostic use only.
- Avoid microbial contamination.
- Do not interchange caps or mix controls from different lots.
- Protect reconstituted material from contamination, evaporation, and repeated freeze–thaw cycles.
- Discard vials showing turbidity or precipitate after reconstitution.

LIMITATIONS

- Control values are method- and instrument-dependent and may vary between assay systems.
- Not intended for calibration or standardization purposes.
- Results outside the assigned range may indicate procedural or reagent issues that require investigation.

WARRANTY

This product is designed to perform as described on the label and package insert. The manufacturer disclaims any implied warranty of use and sale for any other purpose.

BIBLIOGRAPHY

1. Beutler, E. (1994): G6PD Deficiency. Blood 84, (11), 3613-3636.
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3. A multi-rule chart for quality control. Clin.Chem. 27, 493–501. WHO Guidelines for Paediatric and Neonatal patients sampling.
4. The Basic Concepts of Quality Control Reference: Interval Studies, Diagnostic Efficiency, and Method Evaluation in Quality Control Ayed Dera http://dx.doi.org/10.5772/intechopen.76848.
5. Data on file: Zephyr Biomedicals.

SYMBOL KEYS

Temperature limitation	Manufacturer	Batch Number/ Lot Number
Use by	Consult Instructions for use	*In vitro* Diagnostic Medical Device
Date of Manufacture	Catalogue Number	This way up

Manufactured by:

Zephyr Biomedicals

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