

G6PD QC | Quality Control for Glucose-6-Phosphate Dehydrogenase (G6PD) Activity

INTENDED USE

This product is intended for use as a quality control material to monitor the performance of in vitro colorimetric assays for the determination of Glucose-6-Phosphate Dehydrogenase (G6PD) activity. It is designed to ensure the accuracy and reliability of test results in clinical laboratories.

QUALITY CONTROL

Level 1: 50 U/dL G6PDH (Range: 30-70)

Level 2: 200 U/dL G6PDH (Range: 165-235)

ASSIGNED VALUES

Due to variations caused by test equipment, reagents, and laboratory techniques, the quoted ranges are provided for guidance purposes. It is recommended that these ranges be used until each laboratory establishes its own reference ranges based on its specific requirements.

Thanks to the precise manufacturing process, the control ranges remain consistent across batches. The control range corresponds to the mean $\pm$ 2SD.

STORAGE AND VALIDITY DATE

Storage: This kit should be stored at 2-8°C.

Validity date: Controls are stable until the expiration date stated on the label when stored at 2-8°C

SAFETY PRECAUTIONS AND WARNING

1. For IVD uses only.
2. Do not use the kit after its expiry date.
3. Please handle the reagents with caution, avoid ingestion and contact with eyes and skin.
4. Do not mix kits with different lot numbers.
5. Do not pipette by mouth.
6. The reagents contain sodium azide, do not ingest.
7. The reagents must be used only for the purpose intended by suitably qualified laboratory personnel.

References

- 1) Tietz Textbook of Clinical Chemistry and Molecular Diagnostics, W.B. Saunders Co. Philadelphia (2012).
- 2) Howes RE, Piel FB, Patil AP, et al. G6PD deficiency prevalence and estimates of affected populations in malaria endemic countries: a geostatistical model-based map. *PLoS Med* 2012;9: e1001339.
- 3) Nkhoma ET, Poole C, Vannappagari V, et al. The global prevalence of glucose-6-phosphate dehydrogenase deficiency: a systematic review and meta-analysis. *Blood Cells Mol Dis* 2009;42:267–78.
- 4) Luzzatto L, Seneca E. G6PD deficiency: a classic example of pharmacogenetics with on-going clinical implications. *Br J Haematol* 2014; 164:469–80.
- 5) Cappellini MD, Fiorelli G. Glucose-6-phosphate dehydrogenase deficiency. *Lancet* 2008; 371:64–74.