

## Intended Use

Glucose-6-phosphate dehydrogenase (G6PD) controls can be used to test for the quantitative and qualitative determination of G6PD in blood. For *in vitro* diagnostic use only. **Rx Only**

## Product Description

The G6PD control set is a three level, lyophilized, entirely human blood based control supplied in a 2 x 0.5 ml configuration for each level of the control. Suitable tests and controls for G6PD deficiency should be able to show normal, intermediate (approximately 50% of normal) and very low G6PD activity. The controls in this kit, when used with the Pointe Scientific method will demonstrate normal, intermediate and deficient G6PD activity.

## Warning

G6PD controls are for *in vitro* diagnostic use. Normal precautions exercised in handling laboratory reagents should be followed. Dispose of waste observing all local, state and federal regulations. Refer to material safety data sheets for any updated risk, hazard or safety information.

**Potential bio-hazardous material.** 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. It is recommended such samples be handled at the Centers for Disease Control's Bio-Safety Level 2.

## Storage

- When stored at 2-8°C, the unreconstituted material is stable until the expiration date stated on the vial.
- The reconstituted material is stable for 7 days when stored refrigerated at 2-8°C.

## Procedure

- Remove the controls from the refrigerator.
- Remove stopper and volumetrically add 0.5ml of deionized water. Replace the stopper. Gently swirl to dissolve.
- Allow the controls to stand 15 minutes.
- Invert gently and swirl to assure homogeneity of the contents. Let the controls stand at least 10 minutes. Swirl gently just prior to each use. Avoid foaming. **DO NOT SHAKE.**
- Treat the controls as you would a patient sample and test each level in accordance with the reagent manufacturer's requirement of the test method. Control contains 10-14 g/dl Hemoglobin.
- Recap the controls and return them to 2-8°C when not in use.

## Expected Values

The G6PD values were determined by repetitive assays of the Pointe Scientific 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.

## G6PD Values Direct from the Instrument (U/L)

Lot #: 326501	G6PD	T. Hemoglobin
Normal: Exp. Date: 2025-08-31	1424 ± 427 U/L	12.9 g/dL
Intermediate: Exp. Date: 2025-08-31	605 ± 182 U/L	12.7 g/dL
Deficient: Exp. Date: 2025-08-31	245 ± 159 U/L	13.4 g/dL

## G6PD Values Calculated per mass Hemoglobin (U/gHb)

Lot #: 326501	G6PD	T. Hemoglobin
Normal: Exp. Date: 2025-08-31	11.0 ± 3.3 U/gHb	12.9 g/dL
Intermediate: Exp. Date: 2025-08-31	4.8 ± 1.4 U/gHb	12.7 g/dL
Deficient: Exp. Date: 2025-08-31	1.8 ± 1.2 U/gHb	13.4 g/dL

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## Symbol Key

Use by (YYYY-MM-DD)	Lot and batch code
Catalog number	Manufacturer
<i>In vitro</i> diagnostic medical device	Temperature limitation
Consult instructions for use	<b>Rx Only:</b> Prescription Use Only
CE mark	Authorized representative in the European Community

## Certified to Perform Reagents

The Pointe reagents are certified to be manufactured according to specified parameters. Any Pointe reagent product not meeting specifications through its listed expiration date will be remedied immediately without charge.