

CareStart™ G6PD Biosensor

World's First G6PD Quantitative Test Giving the Result in 4 Minutes

Meridian Healthcare®
medical diagnostics and equipment



CareStart™ G6PD Biosensor

The careSTART™ G6PD Biosensor is intended for the quantitative measurement of G6PD enzyme activity in the whole blood using electrochemical method. The careSTART™ G6PD Biosensor is intended to identify a G6PD deficient individual. Healthcare professionals can diagnose G6PD deficient individual quickly and reliably with this instrument. The Analyzer should be used only with careSTART™ G6PD Biosensor Strip.



- Suitable for neonatal and adult screening
- Internal sensor for temperature calibration
- Store up to 1,000 test results
- Automatic blood loading

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G6PD deficiency is a genetic disorder, resulting in no or low G6PD activity. People with G6PD deficiency should not take primaquine, an antimalarial drug, and other drugs with high oxidative stress because it could cause serious side effects such as acute hemolysis. Now, more countries are implementing G6PD screening as a part of their newborn screening program the careSTART™ G6PD Biosensor is intended for the quantitative measurement of G6PD enzyme activity in the whole blood.


Features

- ✓ **Test Type:** Quantitative point-of-care test
- ✓ **Measurement:** Precise measurement of total G6PD activity
- ✓ **Specimen:** Whole blood
- ✓ **Specimen Volume:** 5 µl
- 🕒 **Result Time:** 4 minutes
- ✓ **Package Size:** 25 strips/pack
- ✓ **Other Specification:** Internal sensor for temperature calibration - Internal memory storing up to 1,000 test results - Automatic blood loading

CareStart™ G6PD Biosensor


Test Procedure

1. Keep the device at room temperature during the test.

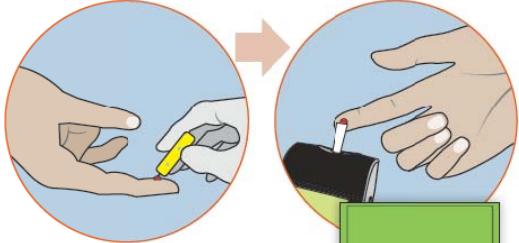


2. Press the power button to turn on the meter. All symbols appear on the display for 1 second and then code number will appear on the display automatically.

3. Insert the test strip with the G6PD side facing up until it does not enter further anymore. A beep will sound. When the blood symbol flashes on the standby mode, preparation for the test is done.




4. Prick a finger, using a lancet. Put the finger with the collected blood at the end of the test strip and completely fill the window of test strip. The



measurement starts automatically and the normalized result at 30 °C appears on the display as U/dL.

The result is automatically stored in the memory.



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Performance

The careSTART™ G6PD Biosensor Strips were evaluated in laboratory and by clinical settings in comparison with a spectrophotometric quantitative method as a reference. The result showed no significant difference between these two methods (Paired t-test, $t=0.02$, $p=0.9855$, $n=60$). In addition, correlation coefficient between spectrophotometric method and careSTART™ G6PD Biosensor Strips was $r=0.9310$, $p<0.0001$ (Pearson Correlation). The range of G6PD enzyme activities in the blood samples used was as shown below:

- ✓ Range tested 10 ~ 215 U/dL
- ✓ Total number of samples: 60

Expected Value

The following range of G6PD activities was obtained for 30 clinically healthy males and females at 20°C ~ 25°C:

Total G6PD Activity 98 – 145 (U/dL)

- ✓ 10 or < 10 U/dl severe deficiency
- ✓ 11 - 35 U/dl moderate deficiency
- ✓ 36 - 67 U/dl mild deficiency
- ✓ 68 - 145 U/dl normal activity



CareStart™ G6PD Biosensor
the world's first commercial G6PD biosensor that enhances sensitivity and accuracy based on electrochemical analysis.

EUROPE Ordering Information:

CareStart™ G6PD Biosensor
Product Code: BGB-E00182
Packaging: 1 each



Meridian Healthcare®

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