

2019

Validation of a diagnostic to identify G6PD deficiency

- 1 Training objectives and agenda
- 2 G6PD overview
- 3 G6PD testing
- 4 SD Biosensor STANDARD
G6PD test

Objectives

1. Review G6PD deficiency and G6PD testing
2. Introduce a point-of-care quantitative diagnostic screening tool: the SDB STANDARD G6PD Test

Target Audience

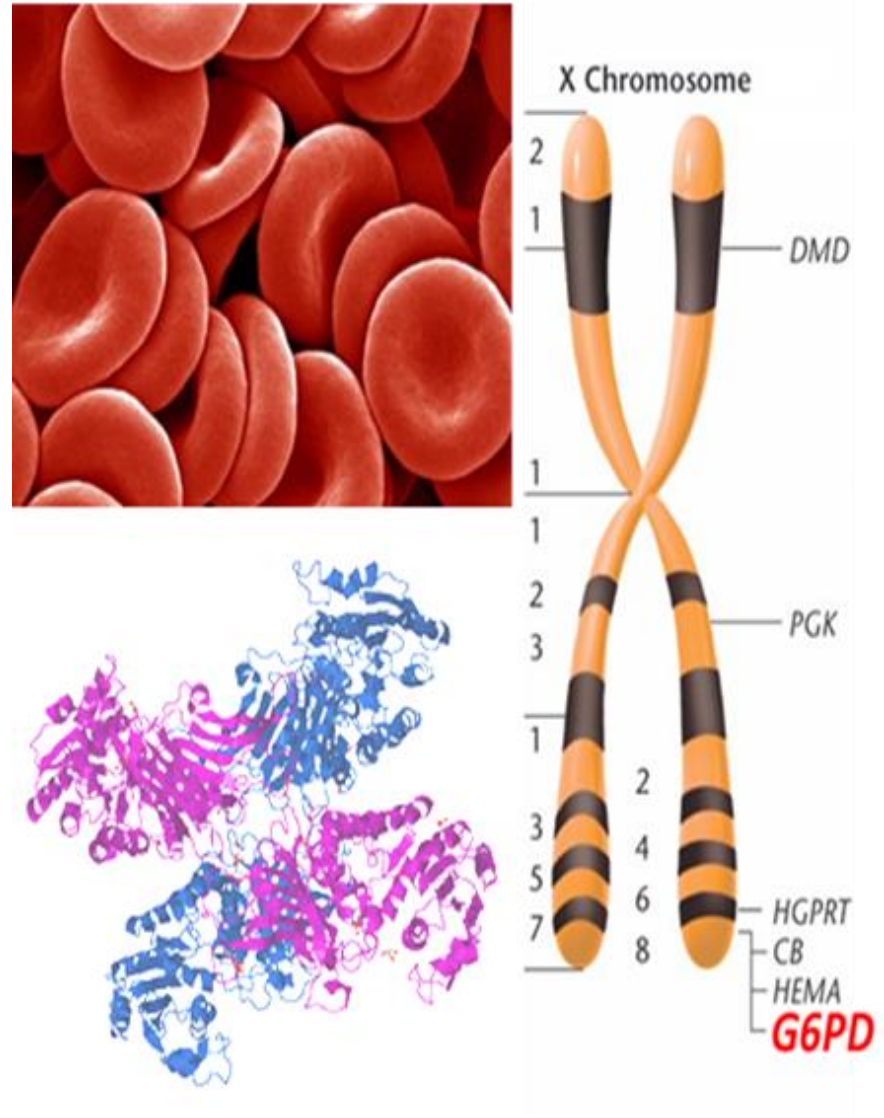
Laboratory technicians or other health workers who will be conducting G6PD testing at the point of care

Training Time

3 hours

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Overview: What do we know about G6PD?



What is G6PD?

Glucose-6-phosphate dehydrogenase (G6PD) is an enzyme that all people have in their bodies.

G6PD is important for red blood cells and their ability to respond to oxidative stress. Oxidative stress can be triggered by:

- Taking certain medications
- Eating certain foods (e.g., fava beans)
- Putting certain substances on the skin (e.g., henna)
- Some infections

If someone has low G6PD enzyme, their red blood cells can break down (hemolysis) when the body is exposed to these triggers.

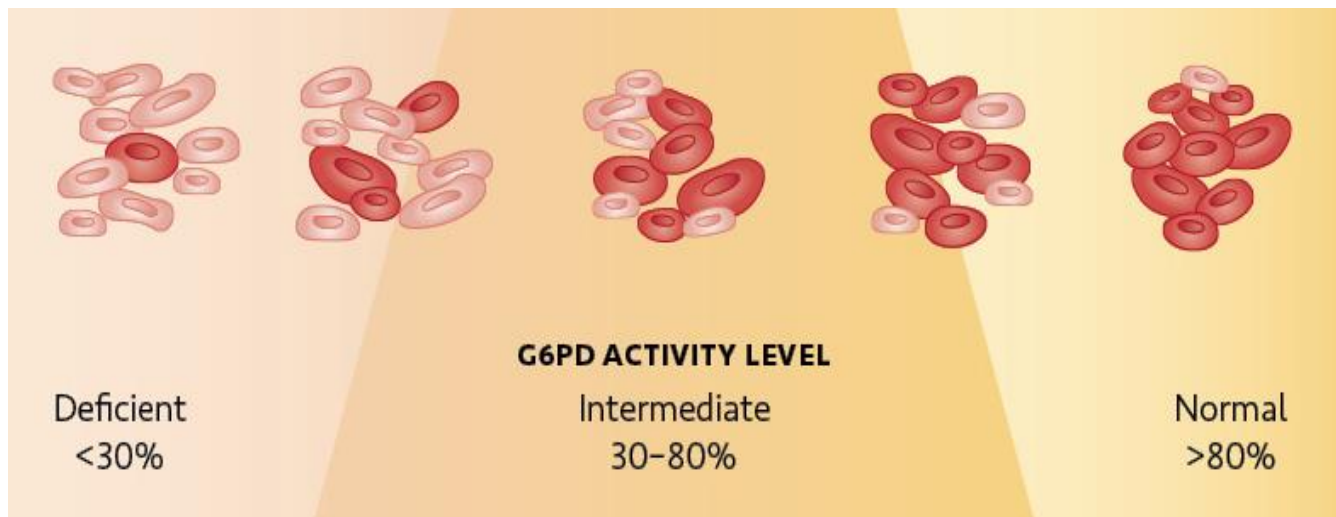
Acute hemolytic anemia (AHA) happens when red blood cells are destroyed faster than the body can replace them. AHA can lead to life-threatening anemia requiring blood transfusions or kidney failure.

G6PD Status

G6PD Status can be categorized as deficient, intermediate, or normal.

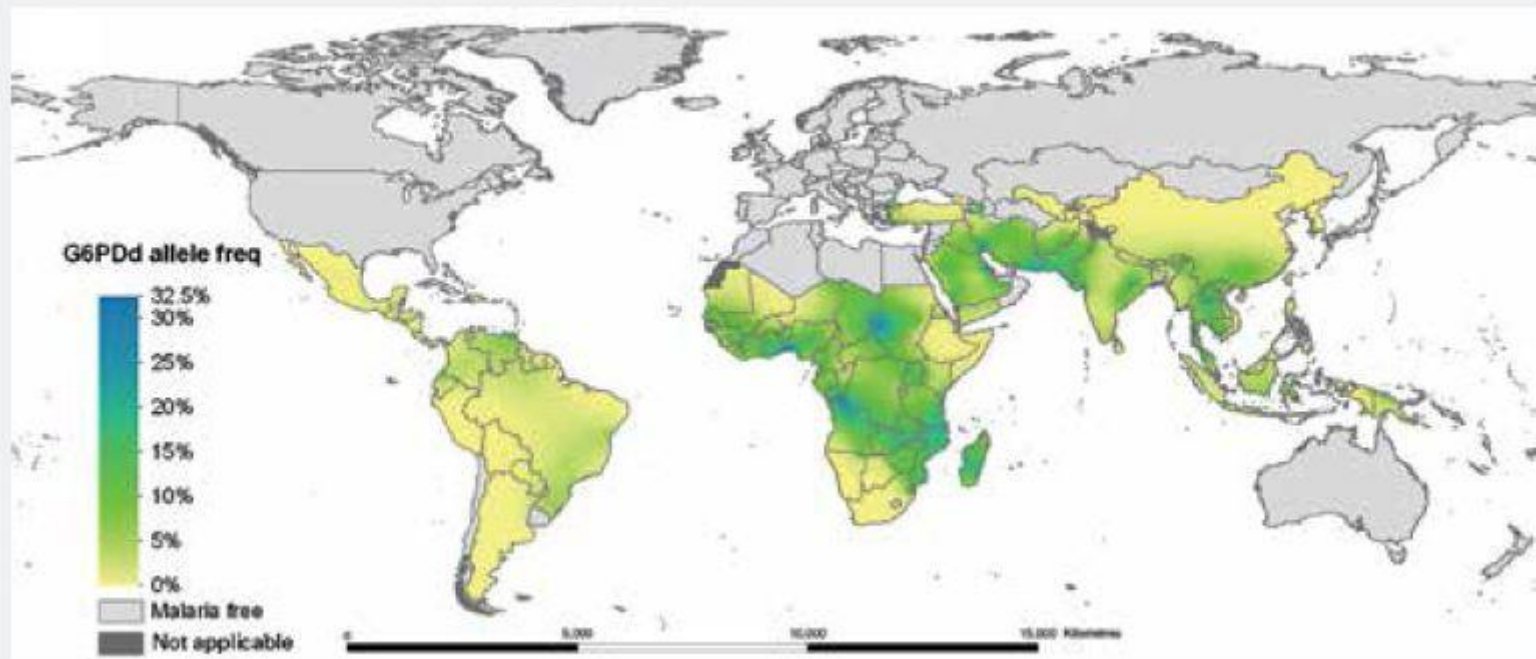
People can have a mix of red blood cells – some with low G6PD activity and some with high G6PD activity.

- If someone has mostly red blood cells with low G6PD activity, they are considered G6PD deficient.
- If someone who has mostly blood cells with high G6PD activity, they are considered G6PD normal.
- If someone has mixed blood cells, with high and low activity, they are considered G6PD intermediate. Only females can be considered G6PD intermediate.



Global prevalence of G6PD deficiency

Estimated G6PD deficiency allele frequencies



Source: Howes et al. (2013)

Why test for G6PD status?

Three primary reasons for G6PD testing:

Radical cure of *P. vivax* malaria: Recommended treatment for clearing liver-stage parasite is a drug called primaquine, which can cause life-threatening hemolysis in patients with G6PD deficiency.

Neonatal screening: Newborn infants with G6PD deficiency are at risk of hyperbilirubinemia, which can progress to kernicterus (brain damage resulting from severe jaundice), often a fatal condition.

Other medications: Hemolytic anemia may be triggered by specific antibiotics and anti-inflammatory drugs in patients with G6PD deficiency.

P. vivax treatment guidelines by G6PD status

G6PD status	Recommended treatment
G6PD deficient	Consider preventing relapse by giving primaquine (PQ) once a week for 8 weeks with medical supervision
G6PD intermediate	Decision to prescribe PQ based on an assessment of risks and benefits*
G6PD normal	Treat in children and adults** with 14-day course in all transmission settings
G6PD status unknown or testing unavailable	Decision to prescribe PQ based on an assessment of risks and benefits***

* *Except pregnant women, infants aged < 6 months, women breastfeeding infants aged < 6 months, women breastfeeding older infants unless they are known not to be G6PD deficient and people with G6PD deficiency.*

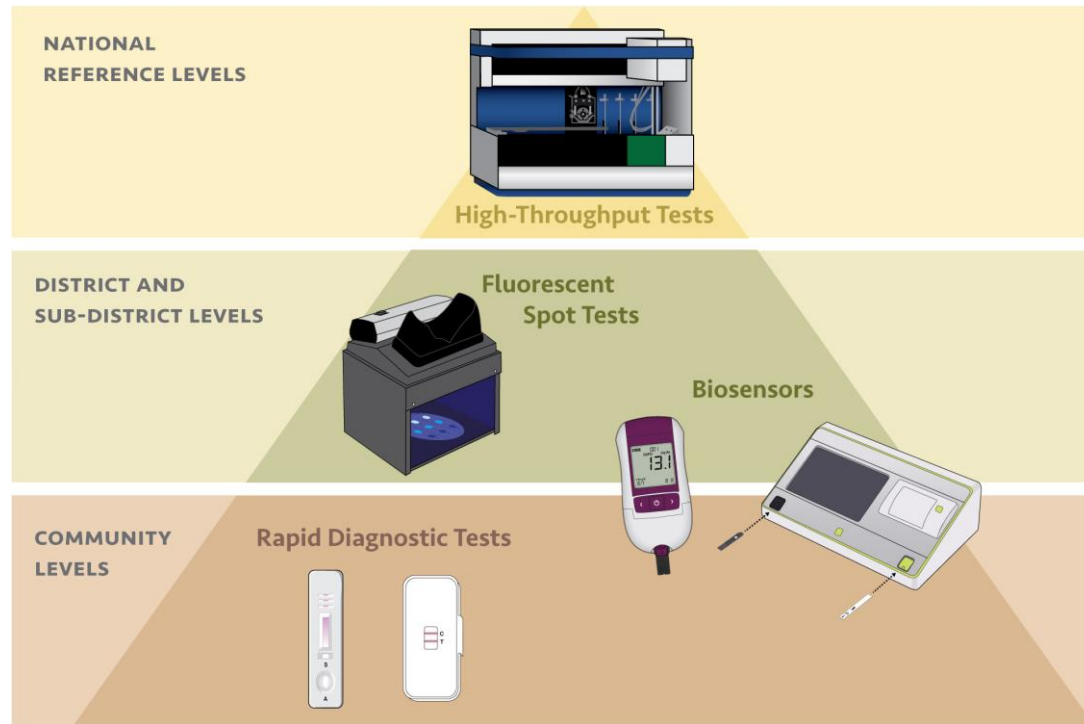
** *Risks include low relapse rates, low *P. vivax* incidence rates, high G6PD deficiency prevalence, patient unable to detect signs and symptoms of hemolysis, and patient has poor access to health care system.*

*** *Risks include low relapse rates, low *P. vivax* incidence rates, high G6PD deficiency prevalence, inconsistent counseling of patients regarding signs and symptoms of hemolysis, and health facility has limited capacity to manage acute hemolytic anemia.*

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G6PD testing challenges

1. Current G6PD testing methods are not suitable for malaria treatment settings
2. Limited evidence on the performance, accuracy, and usability of new point-of-care tests for G6PD deficiency
3. Use of qualitative tests leads to significant misidentification of G6PD intermediate women

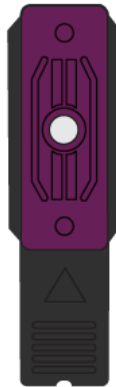


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G6PD test**

SD Biosensor STANDARD G6PD Test



Test Procedure



Components



Test Device



EZI Tube
Sample Collector



Extraction Buffer

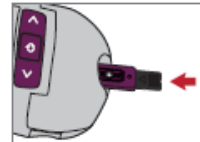


Code chip

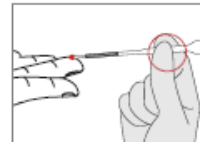


Analyzer

Test Procedure



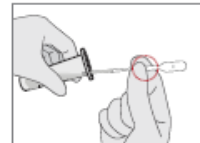
1. Insert test device into analyzer.



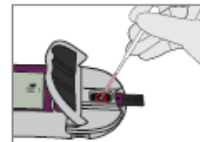
2. Collect blood.



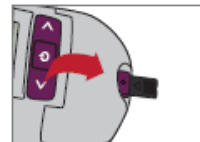
3. Mix blood and buffer 8-10x.



4. Collect mixed sample with NEW sample collector.

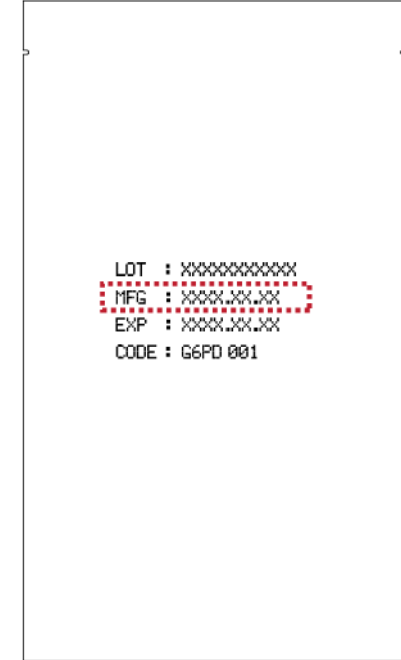
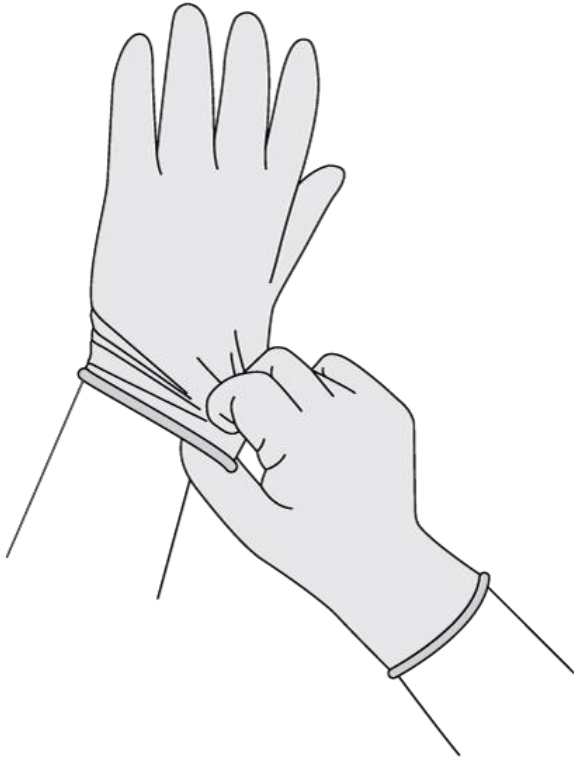


5. Apply mixed sample to test device.

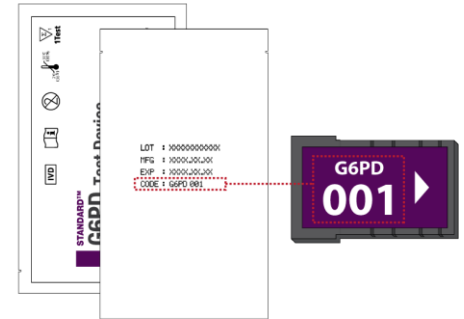


6. Close analyzer flap.

Step 1: Put on new gloves for each patient.
Prepare materials needed – check analyzer
battery and expiration of code chip.



Step 2a : Put on new gloves for each patient.
Prepare materials needed – check analyzer
battery and expiration of code chip.



Step 2b: Insert the new codechip until it snaps
into place.

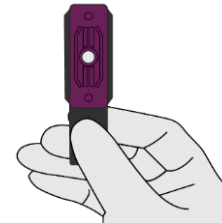
Note: Make sure the analyzer is turned off.
There is a code chip in every kit.
Replace the code chip only when you open a
new kit.



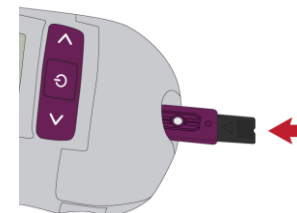
Step 3a : Open the foil pouch with test device and take a test device out.



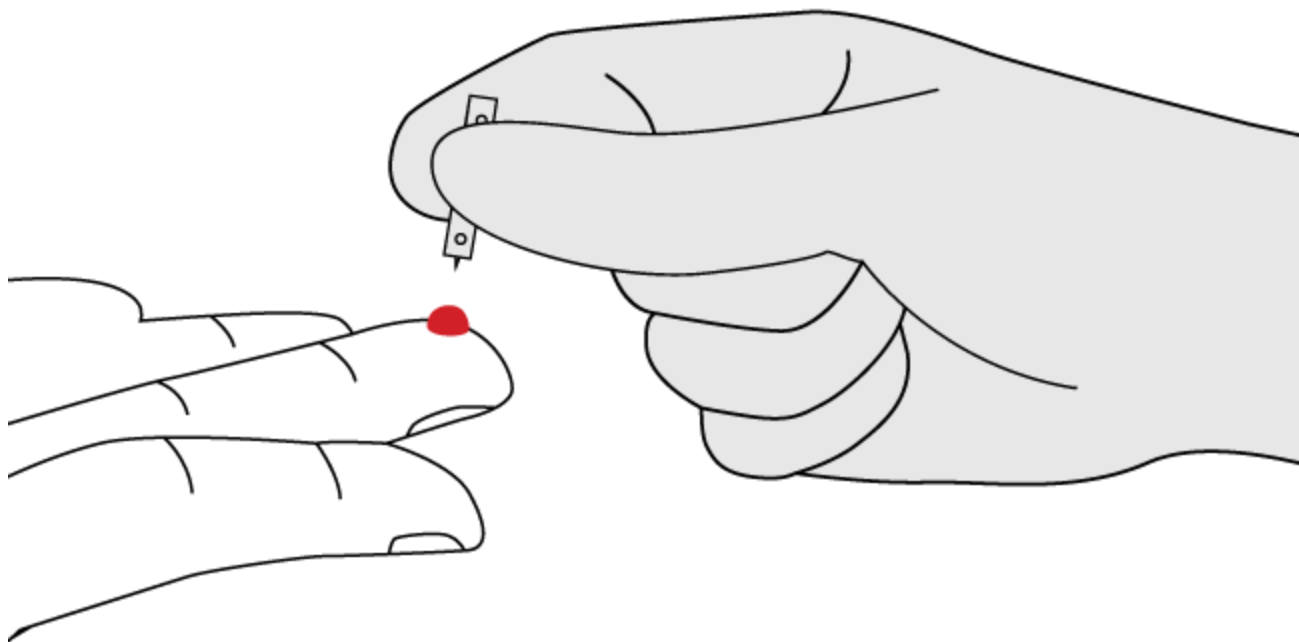
Step 3b: Hold the test device with thumb and index finger so that the upper test device is facing upward.



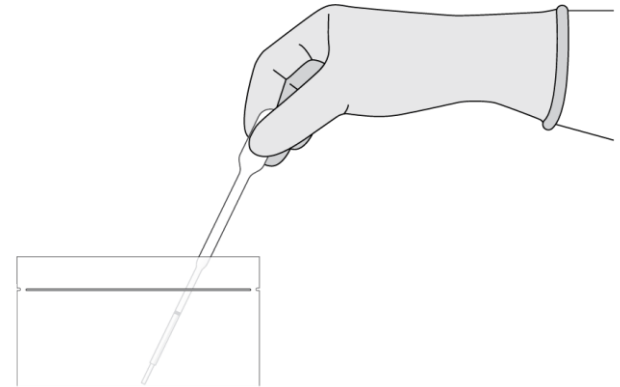
Step 3c: Insert the test device into the test device slot until it will go no further.



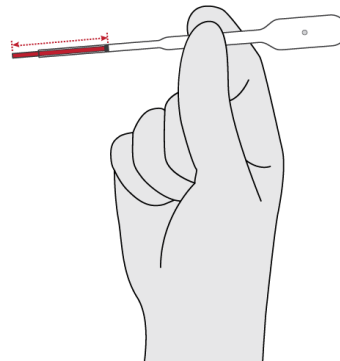
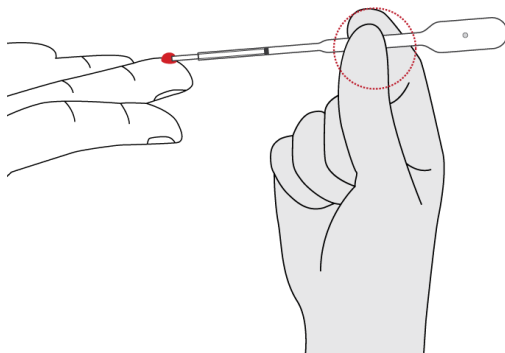
Step 4: Prepare specimen for use – prick finger



Step 5a: Open the sample collector pouch and take out a NEW sample collector.

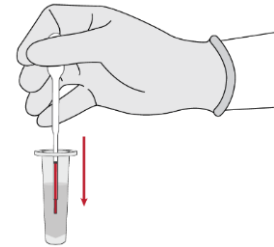


Step 5b: Hold the sample collector horizontally and touch the tip of the sample collector to the blood specimen.

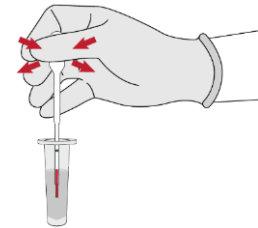


Note: Capillary action will automatically draw the specimen to the black line and stop.

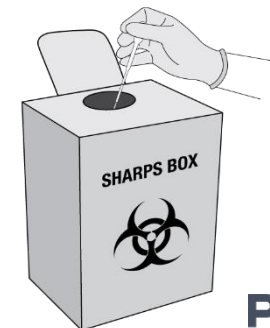
Step 6a: Place the sample collector into the extraction buffer.



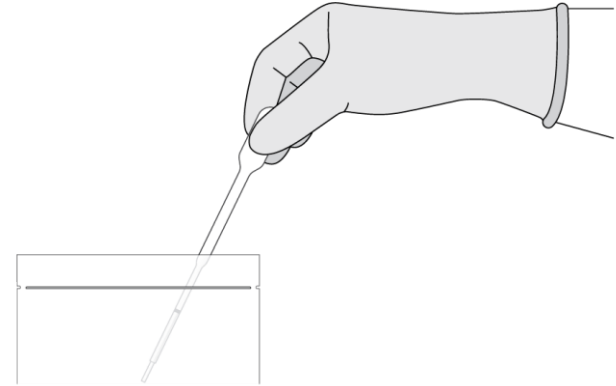
Step 6b: Mix the collected specimen with extraction buffer, pressing and releasing the sample collector 8 to 10 times.



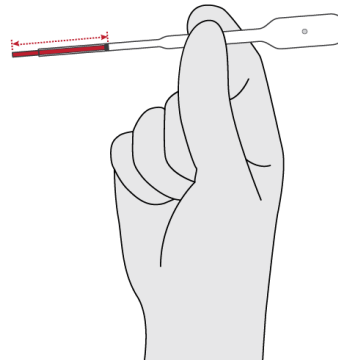
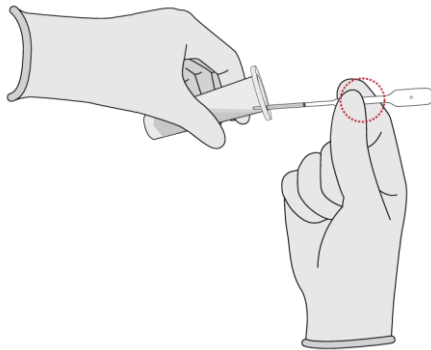
Step 6c: Discard used sample collector in the biohazard box.



Step 7a: Open the sample collector pouch and take out a NEW sample collector.

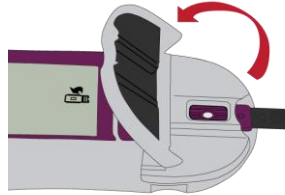


Step 7b: Hold NEW sample collector horizontally and touch the tip of the sample collector to the mixed specimen.

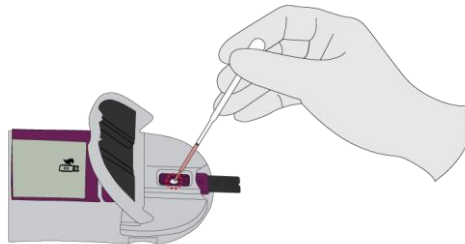


Note: Capillary action will automatically draw the specimen to the black line and stop.

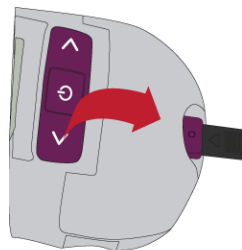
Step 8a: Open the measurement chamber flap.



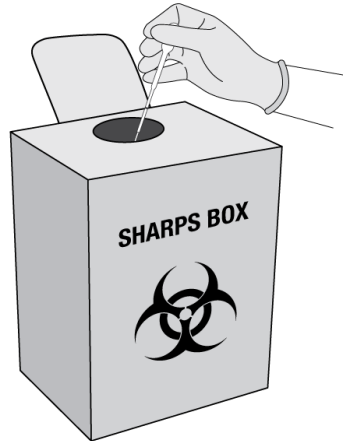
Step 8b: Apply the mixed specimen to the specimen application hole of the test device.



Step 8c: Close the measurement chamber flap IMMEDIATELY after applying.



Step 9a: Discard used sample collector in the sharps box.



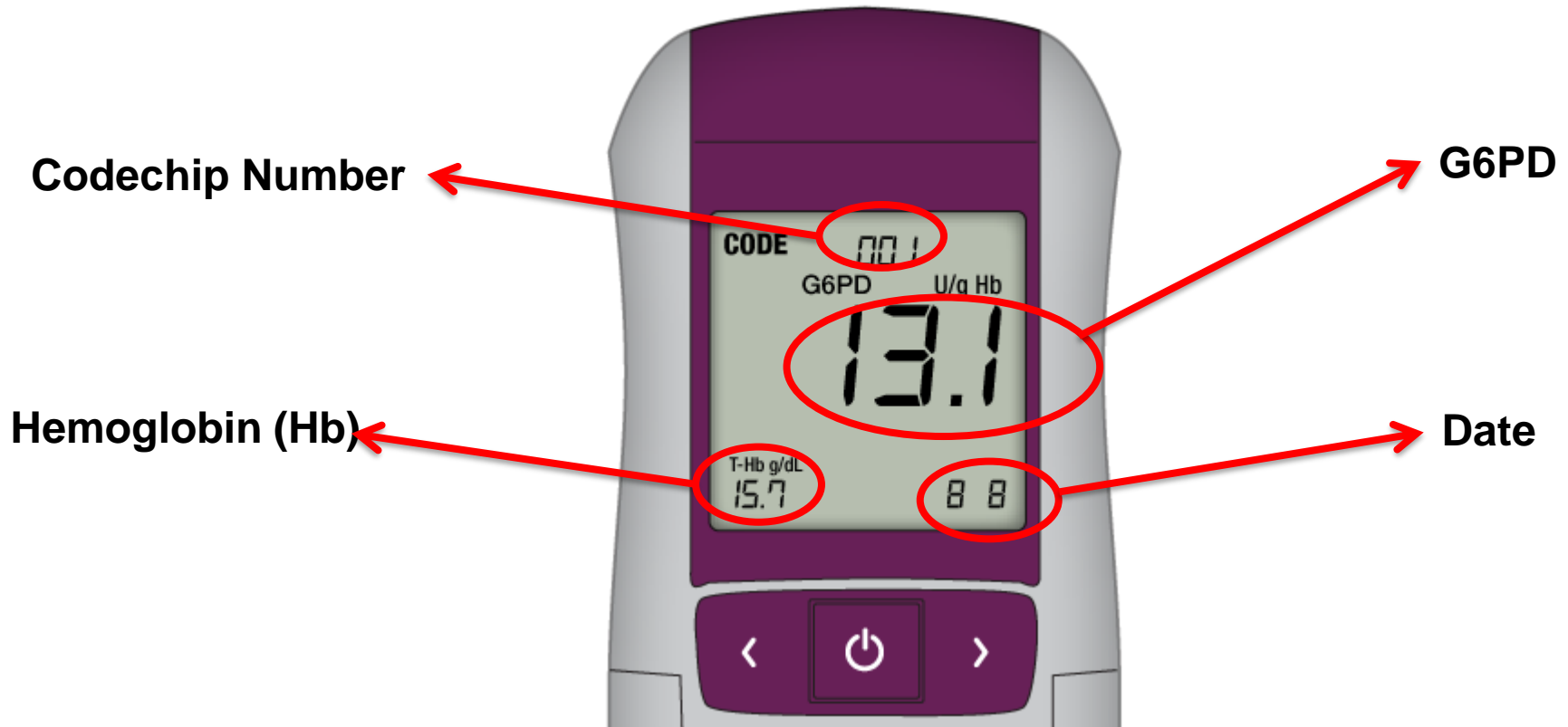
Step 9b: Wait 2 minutes for the test result to appear on the screen.



SD Biosensor G6PD STANDARD Test Video



Results Output



Results Interpretation

Classification	G6PD enzymatic activity (IU/g Hb)	
	Male	Female
Normal (high activity)	≥ 4.0	> 6.0
Intermediate (medium activity)	N/A	4.0–6.0
Deficient (low activity)	≤ 3.9	≤ 3.9

Common User Mistakes

Forgot to calibrate the analyzer.

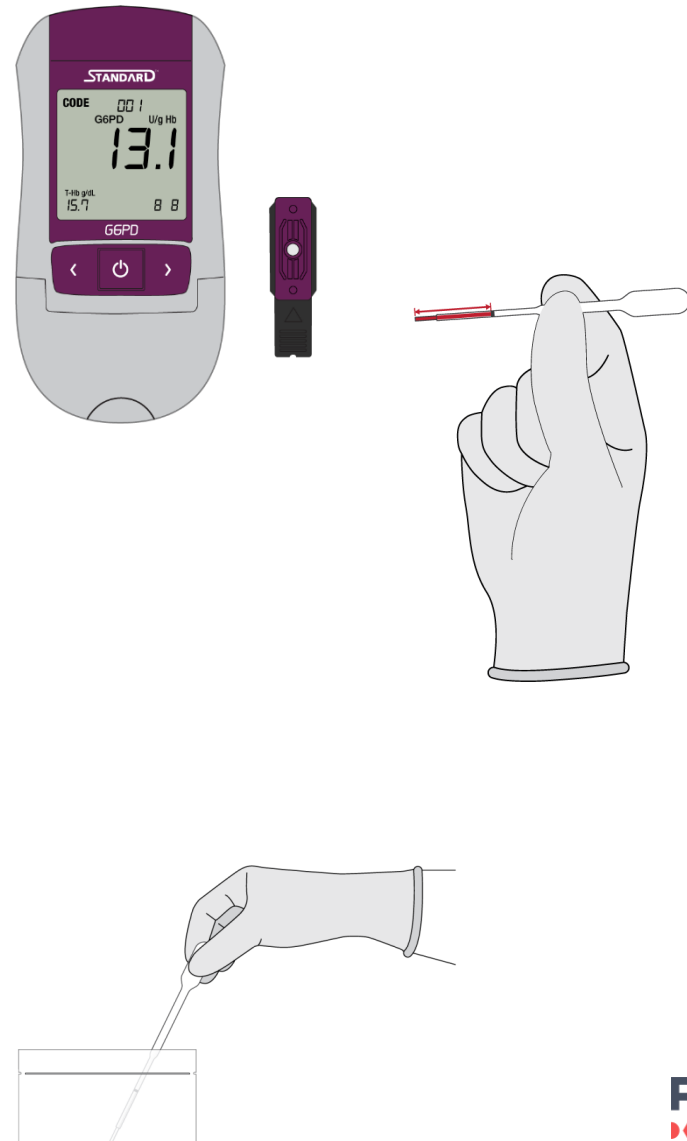
Make sure to calibrate the analyzer if using a new analyzer or a new lot of test devices, or if the analyzer has been dropped.

Did not collect a large enough sample.

Ensure you collect sufficient volume of blood and buffer. Fill the sample collector to the black line.

Used the same sample collector for collecting both blood and buffer.

Dispose of sample collector after blood collection and use NEW sample collector for buffer collection.



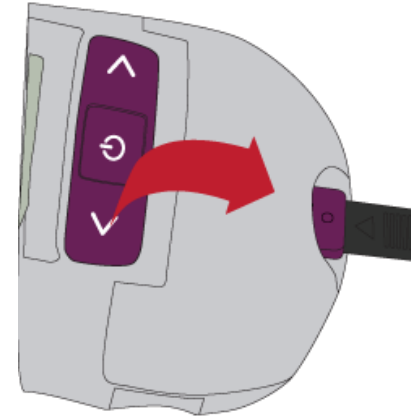
Common User Mistakes (cont.)

Waited too long to close measurement chamber and test timed out.

Close measurement chamber flap immediately after applying specimen.

Read hemoglobin results incorrectly.

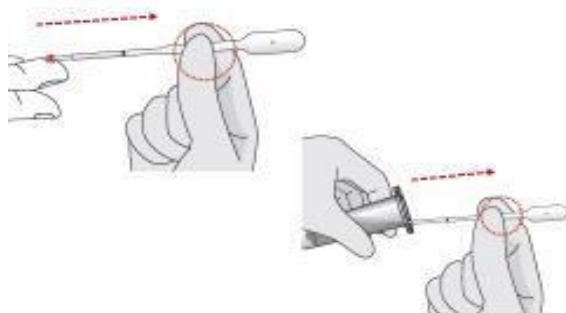
The top right 13.1 U/g Hb indicates units for G6PD measurement. The bottom left 15.7 T-Hb g/dL indicates hemoglobin measurement.



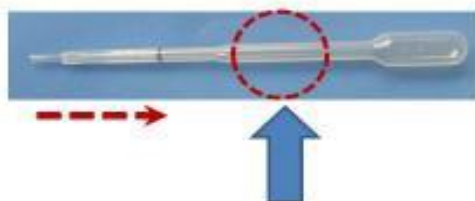
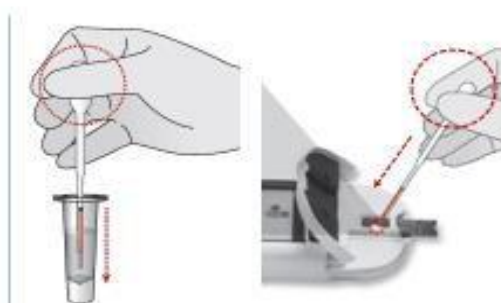
SD Biosensor STANDARD G6PD Test

Tip: How to use EZI tube

TO TAKE UP



TO PUSH OUT



HOLD HERE



HOLD HERE

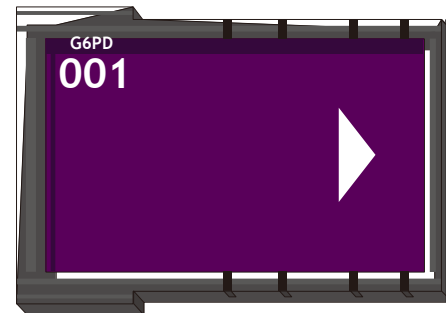
Loading the right amount of blood and the right amount of mix is VERY important in order to have a reliable result.

While holding the EZI tube on the blood drop or on the mix, the liquid will AUTOMATICALLY fill the EZI tube up to the black line.

Do NOT remove the EZI tube too early. When held correctly, the EZI tube will not collect more blood than needed, as it will stop at the black line.

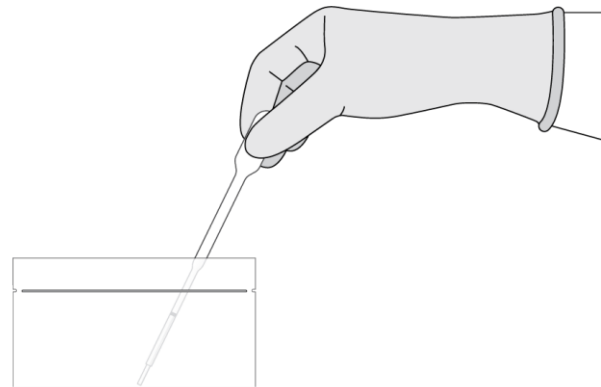
Quiz

How do you use the code chip?



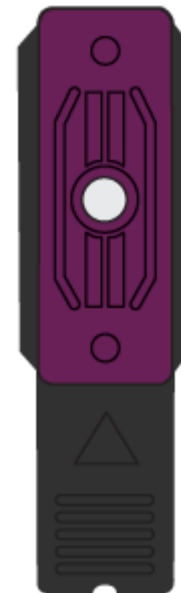
Quiz

How many sample collectors do you need to run one sample?



Quiz

What is the temperature range for test operation?



Quiz

What is the temperature range for test operation?



SD Biosensor STANDARD

G6PD Test IFU

Intended use

The test is intended to aid in the identification of people with G6PD deficiency, providing point-of-care access and allowing prompt treatment decisions.

Kit storage and operating temperature

The sealed pouch containing the test device may be stored at 2°C to 30°C (36°F to 86°F) out of direct sunlight.

Perform test at 15°C to 40°C (59°F to 104°F).

Specimen collection and preparation

Perform test using whole blood (capillary or venous).

If stored venous blood is kept in a refrigerator, the blood can be used for testing 24 hours after collection.

Measuring Ranges

Total hemoglobin: 4-25 g/dL

G6PD: 0-20 IU/g Hb

SD Biosensor STANDARD G6PD Test IFU

Warnings

1. The STANDARD G6PD Test device should only be used with the STANDARD G6PD Analyzer.
2. Calibrate analyzer if using a new analyzer or a new lot of test devices, or the analyzer has been dropped.
3. The test device should not be used beyond the printed expiration date.
4. Make sure that the code chip and the code number printed on the pouch match.
5. The test should be performed at 15°C to 40°C (59°F to 104°F).
6. A test device is for single use only. Do not reuse.
 - Insert a test device and code chip into the test device slot and the code chip slot of the analyzer.
 - Insert a test device into the test device slot with blood application chamber facing up and toward the analyzer.
7. Insert a code chip into the code chip slot with the surface printed with the code number facing up toward the analyzer.
8. Ensure the proper specimen volume for the test device is used. The specimen volume should be 10µl.
9. Insert a test device into the analyzer gently until it will go no further.
10. Do not apply on another site except blood application area of a test device.
11. Do not ingest.
12. Discard the used test devices according to the local guidelines.
13. Extraction buffer contains Triton X-100, which can cause serious eye irritation.

For more information
contact:

**G6PD Operations Research
Community of Practice**
GORCoP@path.org

Community of Practice

The G6PD Operations Research Community of Practice (GORCoP) is a collaboration of researchers, organizations, and clinicians committed to advancing the introduction and scale-up of glucose-6-phosphate dehydrogenase (G6PD) diagnostics in support of safe access to radical cure treatment for *Plasmodium vivax* malaria through operations research. There are several G6PD diagnostics available now and in the pipeline with the potential to expand access to safe radical cure. The GORCoP seeks to understand the transitions that health systems will need to undergo and to inform best practices for undergoing these transitions.

This CoP aims to achieve the maximum impact on health outcomes by harnessing best practices and lessons learned from multiple stakeholders and benefiting from the expertise of participants in areas such as diagnostic introduction, operations research, implementation science, quality assurance, and training.

Resources: [User Proficiency Assessment](#)

