

# SD Biosensor STANDARD G6PD Test

## User proficiency assessment

### Technical Competency Assessment

#### Instructions

Training and competency assessment of STANDARD G6PD Test users should include:

- 1) Demonstration of the test procedure.
- 2) Practicing the test procedure while asking questions with trainer observing.
- 3) Demonstration of test procedure independently.

The technical competency assessment should be conducted using STANDARD G6PD controls.

Site:

Date:

Trainer:

Analyst:

Competencies		Does Not Meet Requirement	Meets Requirement
<b>Pretest procedure</b>			
1	Demonstrates knowledge of key specimen handling/storage requirements		
2	Reads and understands the SD Biosensor instructions for use for G6PD-Hb		
<b>Testing procedure</b>			
3	Observes universal precautions		
4	Checks expiration date of the test kit		
5	Demonstrates proficiency in preparing instrument for analysis including calibration with code chip		
6	Understands storage and labeling requirements for assay reagents and controls		
7	<i>If using G6PD controls—properly reconstitutes G6PD controls and prepares them for analysis</i>		

8	Demonstrates proper sample collection technique		
9	Demonstrates proper mixing and application to strip		
10	<i>If using G6PD controls—successfully performs the assay with controls, by obtaining values that are "in range" with package insert (REMINDER: Only use control mode when running the controls. Never use the device in control mode when running patient samples)</i>		
11	Properly records both G6PD and hemoglobin values into the records		
12	Understands and interprets errors as per user instruction		
13	Demonstrates reproducibility, by obtaining similar values for the controls upon repeating the assay		

Result of Technical Competency Assessment	Completed	PASS (control data within range)	NOT PASS (control data NOT within range)
Watch demonstration of procedure from trainee		N/A	N/A
Perform procedure under observation		N/A	N/A
Capable of doing all the activities independently			

\_\_\_\_\_  
**Analyst's signature**

\_\_\_\_\_  
**Date**

\_\_\_\_\_  
**Supervisor's signature**

\_\_\_\_\_  
**Date**

\_\_\_\_\_  
**Evaluator's signature**

\_\_\_\_\_  
**Date**

## Label comprehension and results interpretation questionnaire

*This questionnaire is intended to assess the user's ability to understand the product label and instructions for use and interpret the results. For the results interpretation component of the assessment, the trainer should use local ranges for normal, intermediate, and deficient or the ranges in the product instructions for use.*

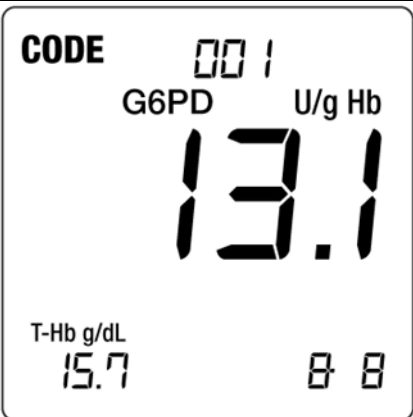
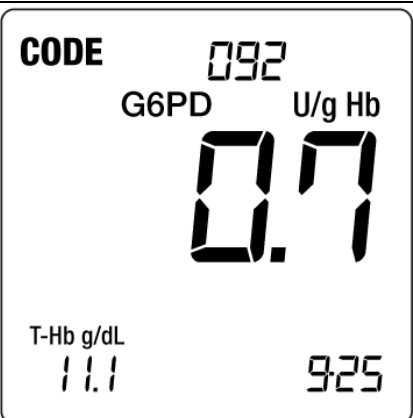
Circle the correct answer for multiple choice questions. (On this version—correct answers are in bold.)

1. The STANDARD G6PD test can be used to identify people who have G6PD deficiency.
  - a. **Yes.**
  - b. No.
2. What does the STANDARD G6PD test measure?
  - a. Presence of antibodies.
  - b. Presence of antigen.
  - c. **Enzyme reaction.**
  - d. None of the above.
3. What is the operating temperature range for test operation?
  - a. 2°–30°C.
  - b. **15°–40°C.**
  - c. Must be performed in an air-conditioned lab.
  - d. 0°–40°C.
4. The SD Biosensor STANDARD G6PD test can be used with which types of samples?
  - a. Capillary blood.
  - b. Venous blood.
  - c. Plasma.
  - d. **Both capillary and venous blood.**
5. How do you use the code chip?
  - a. **Make sure the code number printed on the test strip pouch and the code chip match and insert a code chip before starting the testing procedure.**
  - b. The code chip is not necessary.
  - c. The same code chip can be used all the time.
  - d. You need to change the code chip every time you run a new test.



6. When do you insert the test strip into the analyzer?
  - a. Add the sample to the test strip first, and then insert it into the analyzer.
  - b. The test strip remains inserted in the analyzer between samples.
  - c. **After the code chip is entered into the analyzer and before the sample is collected and applied.**
  - d. It doesn't matter when the test strip is inserted into the analyzer.
7. How do you mix the blood sample and the buffer?
  - a. **Add the blood sample to the buffer and mix with the EziTube by pressing and releasing the tube 10 times.**
  - b. Add the blood sample to the buffer and shake 10 times.
  - c. Put the blood sample in another container and pour in the buffer.
  - d. The blood sample and the buffer should not be mixed.
8. After mixing the buffer and the sample, how much of the mixed specimen should be added to the test strip?
  - a. All of the mixed specimen should be added to the test strip.
  - b. It doesn't matter how much, as long as some is placed on the strip and the test will run.
  - c. Use a micropipette to put 20 microliters on the test strip.
  - d. **Use 10 microliters. The black line on the EziTube is the right amount.**
9. After mixing the sample and buffer, how long should you wait before applying the mixture to the test strip?
  - a. Apply after 2 minutes.
  - b. Apply after 5 minutes.
  - c. **Apply immediately.**
  - d. It can be applied at any time.
10. How many Ezi Tubes do you need to run one sample?
  - a. 0
  - b. 1
  - c. **2**
  - d. 3
11. Can you reuse the test strip?
  - a. Yes.
  - b. **No.**

12. How can you avoid any injury caused by this test?
- a. Use gloves.
  - b. Do not ingest.
  - c. Discard the used test devices according to the local guidelines.
  - d. All of the above.**
13. Which G6PD result are you most likely to see if your patient has very low G6PD activity and is G6PD deficient?
- a. 13.6 U/g Hb.
  - b. 1.2 U/g Hb.**
  - c. Error message.
  - d. 9.7 U/g Hb.

Please read the following test results, record the results, and identify how you would interpret the result.

Number	Result	Record	Interpretation—select one <ul style="list-style-type: none"> <li>• Normal</li> <li>• Intermediate</li> <li>• Deficient</li> <li>• Test did not work (error or NA)</li> </ul>
14	 <p>CODE 001 G6PD U/g Hb 13.1 T-Hb g/dL 15.7 8.8</p>	G6PD U/g Hb _____  Hb g/dL _____	
15	 <p>CODE 092 G6PD U/g Hb 0.7 T-Hb g/dL 11.1 925</p>	G6PD U/g Hb _____  Hb g/dL _____	

16	<div> <div> <b>CODE</b> 017  G6PD U/g Hb  4.5  T-Hb g/dL 13.4 10.4 </div> </div>	G6PD U/g Hb _____  Hb g/dL _____	
17	<div> <div> <b>CODE</b> 076  G6PD U/g Hb  A-A  T-Hb g/dL Lo 9.26 </div> </div>	G6PD U/g Hb _____  Hb g/dL _____	
18	<div> <div> <b>CODE</b> 050  G6PD U/g Hb  2.0  T-Hb g/dL 13.2 9.26 </div> </div>	G6PD U/g Hb _____  Hb g/dL _____	

19		G6PD U/g Hb _____  Hb g/dL _____	
20		G6PD U/g Hb _____  Hb g/dL _____	