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DIAQUICK G6PD Cassette

For the qualitative detection of human Glucose-6-phosphate dehydrogenase in whole blood

REF	Content
Z20103CE	- 25 tests, 25 filter caps, 25 buffer tubes, 25 micro-dropper - 1 package insert

For professional in vitro diagnostic use only.

GENERAL INFORMATION

Method Formazan method
Shelf life 18 months from date of production
Storage 1-30°C

INTENDED USE

DIAQUICK G6PD Cassette is an in vitro diagnostic test designed for qualitative detection of human Glucose-6-phosphate dehydrogenase (G6PD) in whole blood.

DIAGNOSTIC SIGNIFICANCE

Glucose-6-phosphate dehydrogenase (G6PD) is a ubiquitous enzyme crucial for redox metabolism in aerobic cells. Insufficient G6PD activity is an especially significant risk to red blood cell because of their role of red cells as oxygen carriers. Red blood cell (RBC) with insufficient G6PD cannot maintain reduced glutathione and are vulnerable to oxidative damage, resulting in an acute haemolysis. G6PD deficiency is the most common human enzyme defect and has no specific treatment. More than 400 million people worldwide are reported to have G6PD deficiency and the most common medical problem associated with G6PD deficiency is a haemolytic anaemia triggered by various causes: drug, food or infection. However, the response to these foods or drugs is different for individuals and difficult to predict. Therefore, individuals with G6PD deficiency should avoid potentially harmful substances and foods; primaquine, an effective and popular drug for malaria, and fava beans are well-known examples. According to the WHO report, from around 130 million births per year, around 4.5 million children with G6PD deficiency are born, who are particularly susceptible to neonatal jaundice and acute haemolytic crises. Approximately 7.5% of the world population suffer from G6PD deficiency and 2.9% of the world population are genetically G6PD deficient. Therefore, preliminarily screening for G6PD deficiency is very important in regions where G6PD deficiency is prevalent.

TEST PRINCIPLE

DIAQUICK G6PD Cassette determines the enzyme activity of G6PD. This assay is based on the formazan method. The whole blood is mixed with blue dye and the reagent is applied to the device. The reaction becomes colourless due to the enzymatic reaction. The test zone will turn to red when the G6PD enzyme activity of the sample is normal. The colour of the test zone will change from olive to blue green depending on the G6PD enzyme deficiency level. The test result is valid when the upper half of the test window, the control zone, turns red.

REAGENT COMPOSITION

- Test devices
- Filter caps
- Buffer tubes
- Micro-dropper
- Instruction for Use

MATERIAL REQUIRED BUT NOT PROVIDED

- Lancet
- Alcohol swab

REAGENT PREPARATION

The test is ready to use.

STORAGE AND STABILITY

Store the test device at 1 to 30°C (34~86°F).
Shelf-life: 18 months from date of production

WARNINGS AND PRECAUTIONS

1. For in vitro diagnostic use only
2. Do not use the test device beyond the expiration date.
3. Keep sealed until usage, once opened use immediately.
4. Do not use the test device if the pouch is damaged or the seal is broken.
5. Do not re-use a device that has been already used.
6. Handle all specimens safely as potentially infectious.
7. The result of test may show false positive or negative. The clinical information (signs and symptoms) should be considered and other confirmative tests should be conducted for diagnosis.

SPECIMEN COLLECTION AND STORAGE

1. Finger puncture whole blood
1) Clean the tip of the index finger with an alcohol pad and let dry.
2) Take a lancet and make a quick deep stab on the side of the index finger.
3) Avoid squeezing the fingertip to accelerate bleeding as this tends to dilute the blood with excess tissue fluid.

2. Whole Blood Specimen
1) Use a tube with EDTA or heparin anticoagulant.
2) Operate the test within an hour after blood sample collection.
Do not use stored blood sample. Use the pipette only if whole blood in a tube is used.

TEST PROCEDURE

1. Open the sealed pouch and place the test device and filter-cap on a clean, dry and level surface.
Note: Once the foil pouch is opened, the device should be used immediately.
2. Make a prick on the tip of the index finger using a lancet.
3. Take 5 µL of whole blood by using the micro-dropper or a pipette.
Note: Use a fresh micro-dropper for each sample to prevent cross-contamination.
Note: Avoid squeezing of the fingertip.
4. Open the buffer tube by removing the cover.
5. Gently insert the capillary part of the micro-dropper to the buffer tube and press the head of the micro-dropper.
6. Poke the filter-cap into the buffer tube and mix gently.
7. Squeeze approximately 2 drops of buffer to fill the sample well of the device.
8. Wait for 5 minutes and read the result.

See the test procedure on the next page.

INTERPRETATION OF RESULTS

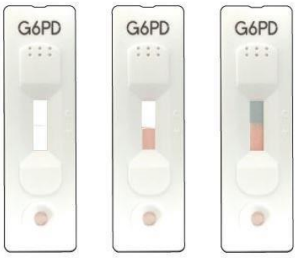
Matched red colour of test zone and control zone of DIAQUICK G6PD Cassette is a sign of normal G6PD activity.

1. Normal
Red appears in both test (T) and control zone (C).

2. Intermediate
Red appears in control zone (C) and its complementary colour (olive) appears in test zone (T).

3. Deficiency
Red appears in control zone (C) and its complementary color (blue green) appears in test zone (T).

4. Invalid
Red does not appear in control zone (C). Do not interpret the result and do a re-test.



QUALITY CONTROL AND CALIBRATION

The red colour of the control zone indicates a sufficient amount of reagent - sample mixture was added and all reagents in the test device are working properly. The absence of proper red colour in the control zone indicates that the test is invalid and should be repeated.

PERFORMANCE CHARACTERISTICS

Analytical sensitivity
The study was performed using G6PD Control 3 levels (Normal: 8.7 U/g Hb Intermediate: 3.5 U/g Hb, Deficient: 0.7 U/g Hb). The G6PD standards used for spiking were commercially available and traceable to the Trinity Biotech G-6-PDH Control. The cut-off level was 5.5 U/g Hb of G6PD as can be seen in the table. There was no variation for the DIAQUICK G6PD Cassette using Quality control standards as samples.

Marker	Standard		Results
	Conc. (U/g Hb)	T-Linie	
G6PD	8,7	-	Negative
	7,9	-	Negative
	7,1	-	Negative
	6,3	-	Negative
	5,5	+	**Positive**
	4,7	+	**Positive**
	3,9	+	**Positive**
	3,1	+	**Positive**
	2,3	+	**Positive**
	1,5	+	**Positive**
	0,7	+	**Positive**

Analytical specificity (Cross-reactivity)
The following related human protein was added to negative and positive samples containing G6PD at 8.7 U/g Hb and 5.5 U/g Hb to test for their potential reactivity in the DIAQUICK G6PD Cassette. All results did not show cross-reactivity with the protein at the following concentration.

Human proteins	Concentrations	Result
6-phosphogluconate dehydrogenase	100 ng/mL	Pass

Interference test
To evaluate the potential for interferences by certain exogenous substance, each compound was prepared by diluting with negative and positive samples, respectively. The concentration of each substance can be found in the following table. The results show that the interfering substances did not affect the expected results.

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Analytes	Conzentration	Analytes	Concentration
Human albumin	20.000 mg/dL	Salicyl acid	50 mg/dL
Sodium citrate	500 mg/dL	Heparin	6 IU/dL
EDTA	800 mg/dL	Glucose	10.000 mg/dL
Bilirubin	2 mg/dL	Caffeine	7 mg/dL
Triglycerides	1%	Cholesterol	5 mg/dL

Clinical sensitivity and specificity
The clinical sensitivity and specificity of DIAQUICK G6PD Cassette were 98% and 100%, respectively. The overall agreement of DIAQUICK G6PD Cassette was 99.4%.

DIAQUICK G6PD Cassette		Quantitative Assay (Spectrophotometry activity assay)			Total
		Normal	Abnormal		
			Intermediate (+)	Deficient (+)	
Normal		120	1	0	121
Abnormal	Intermediate	0	25	0	25
	Deficient	0	5	20	25
Total		120	31	20	171

Relative Sensitivity: 98% (50/51)
Relative Specificity: 100% (120/120)
Overall Accuracy: 99.4% (170/171)

LIMITATIONS

1. DIAQUICK G6PD Cassette is designed for screening of normal levels of G6PD in human blood.
2. This test can provide a fast and easy way to get a test result, but do not completely exclude the possibility of false results caused by various factors. Test results must be evaluated in conjunction with other clinical data available to the doctor.
3. G6PD activity will be lost during storage of blood samples, therefore, tests performed with stored blood may cause erroneous test results.
4. Abnormally low and high haematocrit levels can affect the test performance.
5. Do not mix or use the device and buffer of different lots.
6. Results read after 10 minutes can affect the false-normal result.

WASTE MANAGEMENT

Please refer to local legal requirements.

LITERATURE

1. WHO Working Group, Glucose-6-phosphate dehydrogenase deficiency. Bulletin of the World Health Organization, 1989, 67(6): 601-611.
2. Beutler E., G6PD deficiency. Blood, 1994, 84:3613-3636.
3. Beutler E., Glucose-6-phosphate dehydrogenase deficiency: A historical perspective. Blood, 2008, 111:16-24.

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