Size : 137 x 218 mm

CE

BabySafe™

G6PD Rapid Diagnostic Test

Rapid Test for the Qualitative Determination of Glucose-6-Phosphate Dehydrogenase deficiency (G6PD) in Human Whole Blood Samples

DEVICE

INTENDED USE

This test kit is an in-vitro diagnostic chromatographic assay for the qualitative detection of Glucose-6-phosphate dehydogenase deficiency in Human whole blood.

It assists trained competent users

- in detecting the activity of Glucose-6-phosphate dehydrogenase.

TEST PRINCIPLE:

$$\text{Glucose-6-Phosphate} + NADP^{+} \xrightarrow{G6PD} \text{6-Phosphogluconate} + NADPH \quad \text{- (1)}$$

The specimen travels on the nitrocellulose membrane due to the capillary action and moves further to the test region where Glucose-6-Phosphate (G6P) is converted to 6-Phospho-Gluconate in the presence of enzyme Glucose-6-Phosphate dehydrogenase (G6PD). This reaction pulls 2 electrons from G6P in order to reduce co-enzyme $NADP^{+}$ to NADPH. Further Nitrotetrazolium blue chloride is converted to purple coloured Formazon dye by hydrogen donor with the help of NADPH generated in equation – (1)

$$\underset{\text{Non coloured}}{NADPH + \text{Dye}} \xrightarrow{\text{Hydrogen donor}} \underset{\text{Coloured}}{\text{Dye} + NADP^{+}} \quad \text{- (2)}$$

In G6PD deficient samples there is no colour change and the background of the test strip remains white. Intensity colour formed is proportional to G6PD activity.

INTENDED USER

The test is intended to be performed by a trained user.

SPECIMEN REQUIRED

- **Venous blood:**
  Fresh whole blood collected in EDTA, Heparin or ACD. Freezing is not recommended. With the help of micropipette transfer 5µl whole blood in to the test cassette 'A' region.
- **Capillary blood by Heel prick:**
  Prick the Heel with the help of lancet. Press the heel till blood oozes out freely. Wipe off the initial blood drop. With the help of sample collection device collect the blood sample.

WARNINGS AND PRECAUTIONS:

- Read the instructions carefully before preforming the test
- For in vitro diagnostic use only. NOT FOR MEDICINAL USE. For professional use only.
- Do not use the kit beyond expiry date and do not re-use the test device.
- Do not intermix reagents from different lots.
- Contact with the contents of desiccant pouch containing, among other substances, cobalt chloride (CAS# 7646-79-9) should be kept to minimum. Inhalation / swallowing may cause harm.
- Handle all specimens as if potentially infectious. Follow standard biosafety guidelines for handling and disposal of potentially infectious material.

MATERIALS PROVIDED

A. Individual pouches, each containing:
   1. DEVICE : Test strip assembly impregnated with G6PD assay mixture
   2. Desiccant pouch.

B. BUF : Assay buffer bottle.

C. Package insert.

Colour	C	M	Y	K
Black	0	0	0	100
Green	100	20	100	10

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PRESENTATION

REF	526010010	526010025
Σ	10 T	25 T

OPTIONAL MATERIAL REQUIRED BUT NOT PROVIDED

5µl calibrated micropipettes, micropipette tip.

Materials required but not provided:

Alcohol swab, Sterile blood lancet, Blood collection set, stopwatch.

TEST KIT STORAGE AND STABILITY

- Store the sealed pouches at 2- 8°C .
- Protect the kit from humidity .
- The RDT kit has a shelf life of 24 months from the date of manufacturing as indicated on the pouch.
- The test kit is stable until the expiration date marked on the RDT box and /or the packaging of the individual components when stored as specified.
- DO NOT FREEZE.

TESTING PROCEDURE

Before testing:

1. Prepare all the necessary materials
   - When stored in the refrigerator, bring the kit components to room temperature (Normally it takes minimum 30 to 45 minutes for the same) prior to use.
   - Make necessary preparations of required materials
2. Check the expiration date of the test. (If expired, do not use it but take another test from an unexpired kit).
3. Check that the cassette packaging is not damaged. (If damaged, discard the cassette packaging and use another test).
4. Open the cassette packaging by tearing along the notch indicated and check the desiccant. (If it shows saturation i.e. colour changed from blue to pink or colourless), discard the cassette and take another cassette packaging. If the colour of the desiccant does not show any colour change the cassette can be used for the test.
5. Throw the desiccant in the non-sharp disposal container.
6. Take the cassette and place it on the horizontal surface.
7. The cassette will have:
   - A result window (marked as C & T)
   - A sample port marked “A”.
   - A circle well marked “B”.
8. Write the patient name or patient identification on the cassette.
9. Put the gloves. Use new pair of gloves for each patient.

Test Procedure

Capillary whole blood from Heel prick

1. Wear gloves.
2. Open the packaging of the alcohol swab. Take out the alcohol swab. Do not throw away the empty packaging (wrapper) but keep it aside.
3. Wipe the complete area to be pricked with the alcohol swab.
4. Wait until the area has completely dried (minimum 30 seconds).
5. Place the alcohol swab in the wrapper and set it aside (you will use it again to stop the bleeding after you collected the blood).
6. Take the safety-seal lancet.
7. Detach the cap of the lancet. Puncture the side of the fleshy area with the lancet. Dispose the lancet immediately into the sharps box.
8. Make sure a well-formed drop of blood is present.
9. If there is no well-formed drop of blood, repeat the prick at some other area.
10. Use a new lancet and choose a different puncture site.
11. Take the specimen transfer device and collect 5 µl of blood into the whole blood drop. Take the alcohol swab you put aside (step 5). Press it to the site of pricking to stop the bleeding. After use, put the alcohol swab into the non-sharps

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disposal container.

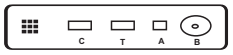
12. Dispense 5 µl blood sample in the sample port 'A', followed by the addition of 5 drops of the Assay buffer in port 'B' (Do not move the device after addition of Assay buffer).
13. Do not read and interpret after 30 minutes.

Venous whole blood

1. Wear Gloves.
2. Collect blood by standard venipuncture procedure into tube containing anticoagulant (EDTA or Heparin).
3. Mix the tube gently.
4. Perform steps 12 -14 of the previous section ("Capillary whole blood from heel prick").

INTERPRETATION OF THE RESULTS

1. At the end of 25 to 30 minutes record the test result as noted in the table below.
2. Where possible have the results confirm by a second reader within this time frame.
3. Colour intensities may vary from faint to strong.
4. Record the test result as noted in the table below:

	**Normal:** Purple colouration at "T" zone compared to "C" zone.
	**G6PD Deficiency:** No colouration at "T" zone.

LIMITATIONS OF THE PRODUCT

1. The test procedure, precautions and interpretation of results for this test must be followed while testing.
2. G6PD deficiency test is a qualitative test kit. It cannot provide the quantitative G6PD assay results.
3. Test kit directly exposed to sunlight and heat can affect the outcome of the test.
4. This is a screening test and has to be confirmed with kinetic assay.
5. Some intermediate samples may behave like normal, depending on RBC count.
6. Young Red cells have a higher G6PD content then the older ones, regardless of the genetic variant that is present, in such cases it has to be confirmed with kinetic assay
7. Normally the activity contributed by WBC, platelets or serum is very small. In case of severe anemia, leukocytosis, or very low G6PDH levels, the use of sample after removing the buffy coat is recommended. Do not use turbid, deteriorated or leaking reagents.
8. This test does not detect intermediate G6PD deficiency.

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23. Data on file: Zephyr Biomedicals.

SYMBOL KEYS

	Temperature Limitation		Manufacturer	DEVICE	Device	Xn NaN, R22, S23-46-61	Harmful if swallowed. Do not breathe vapour. If swallowed, seek medical advice immediately and show this container or label. Avoid release to the environment. Refer to special instructions.
	Use by		Consult Instructions for use	BUF	Assay Buffer		
	Date of Manufacture	REF	Catalogue Number		This side up		
LOT	Batch Number / Lot Number	IVD	*In vitro* Diagnostic Medical Device		Do not use if package is damaged		
Σ	Contains sufficient for <n> tests		Do not reuse				

Manufactured by:

Zephyr Biomedicals

A Division of Tulip Diagnostics (P) Ltd.

M 46-47, Phase III B, Verna Industrial Estate, Verna, Goa - 403 722, INDIA.

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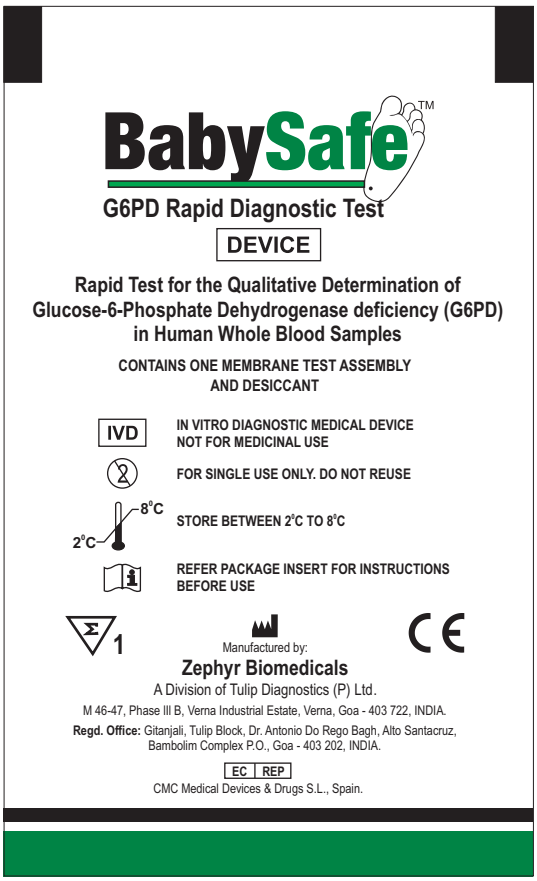
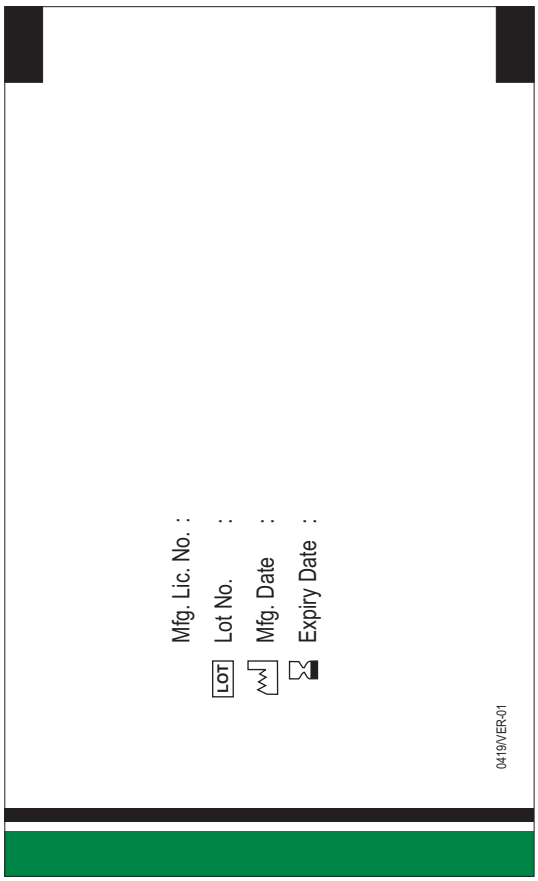
EC REP

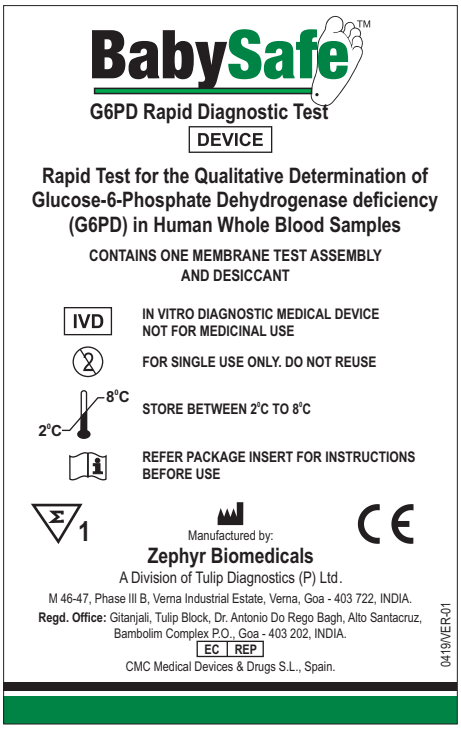
CMC Medical Devices & Drugs S.L., Spain.

0820/VER-01

Size : 70 x 110 mm







Colour	C	M	Y	K
Black	0	0	0	100
Green	100	20	100	10

Size : 100 x 78 mm

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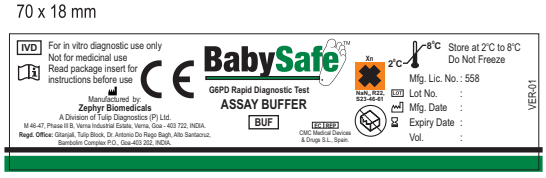
70 x 18 mm



Colour	C	M	Y	K
Black	0	0	0	100
Green	100	20	100	10