

CareStart™ Glucose-6-Phosphate Dehydrogenase Deficiency Screening Test

Rapid One Step G6PD Deficiency Test (Single Strip)

*A rapid test for the screening of G6PD deficiency in human blood
For in vitro test use only*

Intended Use

For the rapid qualitative determination of G6PD enzyme activity in human blood as an aid in the diagnosis of G6PD deficiency

Explanation of the Test

Glucose-6-phosphate dehydrogenase deficiency is a genetic disorder which can cause hemolytic anemia when people with the disorder come into contact with drugs, food and other substances which cause oxidative stress. G6PD deficiency is the most common enzyme deficiency worldwide.

Diagnosis of G6PD deficiency is important in the treatment of disease because many oxidant drugs like anti-malaria drugs, sulfa drugs and ascorbic acid cause a hemolytic anemia especially for the G6PD deficient patients. Therefore, it is highly recommended to test G6PD deficiency in patients before the treatment of oxidant drugs, especially for malaria patients, to protect severe hemolytic anemia.

The CareStart™ G6PD deficiency Test contains a strips in test device. The kit comprises of a single layer strip contained G6PD assay mixture. The assay is based on formazan method using tetrazolium compound. A whole blood sample for normal in G6PD activity produces purple color in reading window as it migrates to the strip. A whole blood sample for deficient in G6PD activity shows no color in reading window.

Materials provided

CareStart™ G6PD Test Kit contains following items to perform the assay:

- Test Device
- Assay Buffer
- Sample Pipette

Precautions

In order to obtain reproducible results, the following rules must be followed:

- 1) For *in vitro* diagnostic use only.
- 2) Open pouch just before use it. Do not expose test kit to fluorescent light for more than 10 min. because reagents on test strips are light sensitive.
- 3) Allow test kits to equilibrate at room temperature (18°C – 30°C) before use
- 4) Do not mix items from different lots of test kits.
- 5) Use disposable gloves while handling potentially infectious material and performing the assay. Wash hands thoroughly afterwards.
- 6) Do not use it beyond the expiration date
- 7) Do not eat or smoke while handling specimens.
- 8) Clean up spills thoroughly using an appropriate disinfectant.

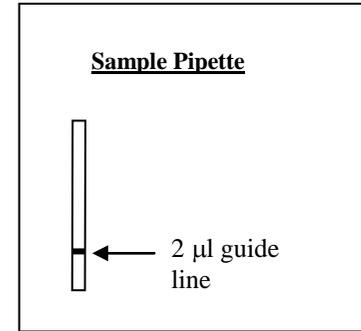
Specimen Collection and Storage

[Collection by venipuncture]

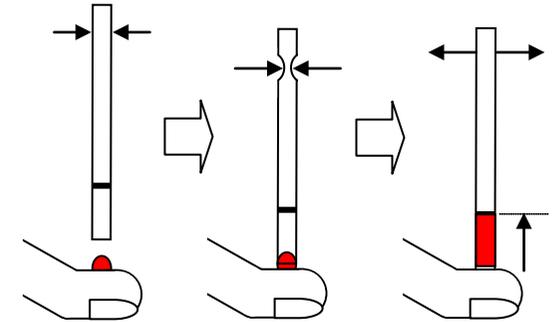
- 1) Collect the whole blood into the collection tube (containing EDTA, citrate or heparin) by venipuncture.
- 2) If specimens are not immediately tested, they should be refrigerated at 2 ~ 8°C. For storage periods greater than three days, freezing is recommended. They should be brought to room temperature prior to use. Using the specimen more than three days can cause non-specific reaction.
- 3) When storage is at 2 ~ 8°C, the whole blood sample should be used within three days.

[Collection using a lancet]

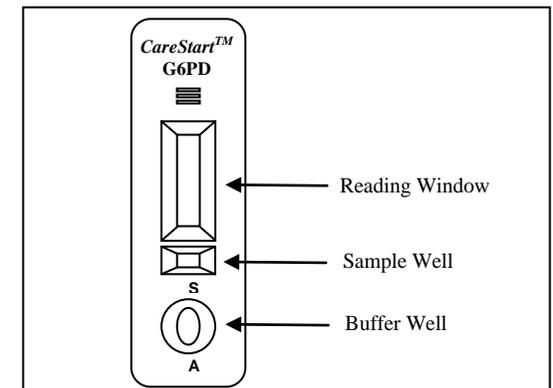
- 1) Clean the area to be lanced with an alcohol swab.
- 2) Squeeze the end of the fingertip and pierce with a sterile lancet provided.
- 3) Wipe away the first drop of blood with sterile gauze or cotton.
- 4) Take a sample pipette provided, while gently squeezing the tube, immerse the open end in the blood drop and then gently release the pressure to draw blood into the sample pipette up to black line.



- 1) Gently squeeze the tube
- 2) Immerse open end in blood
- 3) Gently release to draw blood

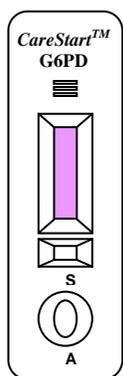


Test Procedure

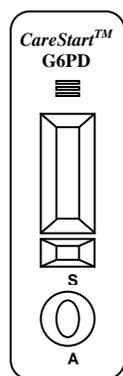


- 1) Add 2 µl of whole blood into Sample Well (small well) by squeezing Sample Pipette.
- 2) **Immediately** Add 2 drops (60 µl) of assay buffer into Buffer Well.
- 3) Read the test result in 5- 10 min.

Interpretation of the test



Normal



Deficiency

1) Normal

A distinct purple color appears in reading window within 10 min.

2) deficiency

No purple color appears in reading window within 10 min

Caution: Do not read test results after 10 min.

Limitations and Interferences

- 1) The test procedure, precautions and interpretation of results for this test must be followed when testing.
- 2) The *CareStart*TM G6PD deficiency Test is qualitative test kit. It cannot provide the quantitative G6PD assay results.

- 3) The variation of individual hematocrit level can affect the test result. Abnormally low hematocrit blood sample can cause the false-deficient result and abnormally high hematocrit blood sample increase the risk of a false normal result.
- 4) Test kit directly exposed to sun-light, fluorescent light and heat can affect the false-normal result.

References

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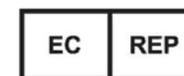
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