Hysen Biotech

G6PD Test Kit

Package Insert

【INTENDED USE】

This test kit is used for qualitative detection of normal or deficient G6PD enzyme activity in whole blood samples. It is suitable for in vitro clinical auxiliary diagnosis of glucose-6phosphate dehydrogenase deficiency.

【SUMMARY】

Glucose-6-phosphate dehydrogenase (G6PD) deficiency is caused by a defect in the G6PD enzyme of red blood cell membranes, resulting in a decrease in the coenzyme of glutathione reductase in the pentose phosphate pathway, namely reduced nicotinamide adenine dinucleotide phosphate (NADPH) production. This leads to a reduction in the generation of reduced glutathione, which is responsible for maintaining the stability of red blood cell membranes, and the inability to resist oxidative damage. Ultimately, it results in red blood cell destruction and hemolysis, which is a hereditary disease. Patients often develop symptoms after consuming fava beans, commonly known as "favism". The G6PD gene is located on the X chromosome, and the disease is an X-linked genetic disorder. Therefore, male carriers of the mutation usually exhibit a dominant phenotype. Homozygous or compound heterozygous mutations in females can also manifest as a dominant phenotype. However, most female carriers with a single heterozygous mutation are asymptomatic carriers, and only a small percentage may develop G6PD deficiency. Since G6PD is the rate-limiting enzyme in the pentose phosphate pathway, patients with G6PD deficiency are unable to metabolize glucose properly. When exposed to oxidative substances such as fava beans, aspirin, and sulfonamide drugs, they may experience acute hemolytic reactions, resulting in jaundice, mental impairment, and in severe cases, rapid breathing, heart failure, and even shock, posing a threat to life. The measurement of G6PD enzyme activity has important clinical significance.[1]

【PRINCIPLE】

This product is based on the glucose-6-phosphate substrate colorimetric method. In the presence of NADP, glucose-6-phosphate is oxidized by G6PD enzyme in the sample, resulting in the production of 6-phosphogluconic acid lactone and NADPH. The light yellow nitrotetrazolium blue chloride (NBT) is reduced to insoluble blue-purple crystalline formazan in the reaction between NADPH and phenazine methosulfate (PMS). When G6PD enzyme activity is normal, insoluble blue-purple crystals are formed. Hemoglobin in the sample is removed by the filtration membrane, allowing the purple crystals to bind to the membrane, forming a blue-purple circular spot. However, when G6PD enzyme activity is abnormal or reduced, the blue-purple circular spot cannot be formed.

【MAIN COMPONENTS】

Component	Ingredient
Card	Cartridge, absorbent pad, percolating membrane
Buffer	Deionized water, PBS
Tube	NBT, NADP, glucose-6-phosphate

【STORAGE CONDITION AND VALIDITY PERIOD】

Storage conditions: sealed dry storage, 2-30℃ room temperature storage.
Validity period: 12 months.
The treatment pipe should be used within 20 minutes after opening the bag, and the storage environment temperature is 4-30°C, and the humidity is not more than 80%; The sample treatment solution should be covered immediately after use, stored in a cool place or refrigerated refrigerator, and used within the validity period. Production date and expiration date: see outer box.

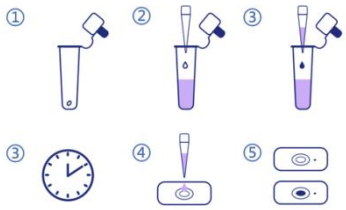
【SAMPLE REQUIREMENTS】

Blood sample: Fresh blood in a non-condensed state, or whole blood with anticoagulant added. The blood sample should be treated with the sample treatment solution provided by this kit in time. If it cannot be treated in time, it should be stored at 2-8°C for no more than 3 days. Store at-18°C for no more than 2 months, freeze at -80°C for no more than 12 months, and freeze and thaw no more than 1 time; Do not centrifuge the treated sample before testing.

【DIRECTIONS FOR USE】

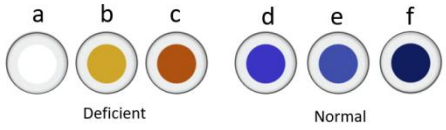
Please read the instructions carefully before testing and restore all reagents to room temperature (25°C±5°C). The test should be carried out at room temperature.
Please read the instructions carefully before operation and prepare a timer.

1. Reagent preparation: take out the Buffer a Tube in the kit and open the lid of the Tube.
   Note: there are 2 reagent pads in the Tube. Make sure that the reagent pad is int the Tube.
2. Add buffer and sample: add 300 μL Buffer to the Tube and shake well so that the colored matter on the reagent pad is dissolved in the Buffer. Note: The reagent pad is insoluble. Take 10 μL blood sample, add it into the Tube, mix well and start timing.
3. Wait 10 minutes.
4. Percolation: take out one Card, drop the reacted buffer to the hole of the Card, generally about 1 minute the liquid will be completely permeated, the result can be interpreted.



【RESULT INTERPRETATION】

The following results may appear, and the explanations are as follows:



1. Deficient: The center color of the detection card is pink, white or yellow (a,b,c).
2. Normal: The center of the card is apparently blue, blue-purple or black (d,e,f). The spots can be rings, and the rings are blue-purple (e).

【PRECAUTIONS】

1. This reagent is for in vitro diagnostic use only. Please read the instructions carefully before testing.
2. This reagent is for one-time use only. Do not reuse.
3. This reagent must be used within the specified shelf life.
4. Strictly follow the instructions and do not mix different batches of test cards and sample extraction solutions.
5. Operational errors or insufficient sample volume may lead to deviations in test results.
6. Do not use the product if the plastic packaging of the test card is damaged.
7. Do not inhale the sample extraction solution.
8. The aluminum foil bag contains a desiccant and should not be ingested.
9. Store strictly according to the requirements in the instructions.
10. The reagent pad in the handling tube contains a small amount of powder that should not be removed. The splashed powder may cause irritation to the skin and eyes. If the solution comes into contact with the skin or eyes, rinse with plenty of water. Seek medical attention if skin irritation or discomfort occurs.
11. Strictly control the reaction time during operation, as excessively long reaction time may result in false negatives.
12. This test card is one of the auxiliary diagnostic methods and the test results are for reference only. They should not be the sole basis for clinical diagnosis and treatment. Positive results need to be further confirmed by other methods. This reagent is for qualitative testing and cannot be used for quantitative analysis.

【LIMATIONS】

1. This kit is used to distinguish normal levels of G6PD enzyme activity from lack of enzyme activity and cannot be used to assess the extent of deficiency. It cannot be used for quantitative testing of G6PD enzyme in samples.
2. Abnormally low and high hematocrit levels can affect test performance. G6PD is usually found in red blood cells, and a low erythrocyte specific volume indicates a low number of red blood cells in a particular volume of blood. Therefore, a lower erythrocyte specific volume increases the risk of false defect results in other normal samples because there are fewer red blood cells resulting in insufficient total G6PD enzymes. In contrast, a similar situation may be present in a sample with a high erythrocyte volume, in which a large number of red blood cells are present, compared to a normal sample. In this case, a high hematocrit increases the risk of a false normal outcome.

【BIBLIOGRAPHY】

1. A Simple Method for Detection of Erythrocyte Glucose-6-Phosphate Dehydrogenase Deficiency (G-6-PD Spot Test) V. Fairbanks, E. Beutler

Index of Symbols

	Consult instruction for use		Tests per kit	EC REP	Authorized Representative
IVD	For in vitro diagnostic use only		Use by	②	Do not reuse
2°C 30°C	Store between 2-30℃	LOT	Lot Number	REF	Catalog #
	Do not use if package is damaged	CE	The products conform to essential requirements		

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