Glucose-6-Phosphate Dehydrogenase (G-6-PD) Assay Kit

Method:Glucose-6-Phosphate Substrate

Cat.NO.	Package Size
GSG6PD	R1：1×60 mL R:21×20mL Lyse：4×70 mL
GSG6PD/B	R1: 2×60 ml R2: 2×20 ml Lyse：6×95 mL
GBG6PD	R1: 1×60 ml R2: 1×20 ml Lyse：4×70 mL
GHG6PD	R1: 1×45 ml R2: 1×15 ml Lyse：3×70mL
GTG6PD	R1: 1×45 ml R2: 1×15 ml Lyse：3×70mL
GXG6PD	R1: 1×60 ml R2: 1×20 ml Lyse：4×70 mL
GKG6PD	R1: 1×60 ml R2: 1×20 ml Lyse：4×70 mL
GDG6PD	R1: 12×3.8 ml R2: 6×2.6 ml Lyse：3×70 mL
TGSG6PD	R1: 1×45 ml R2: 1×15 ml Lyse：3×70mL

This assay kits apply to biochemistry analyzers: Hitachi7020/7080/7180, AU400, DXC800, Dimension RXL Max,TBA40FR,etc.

INTENDED USE

For quantitative determination of Glucose-6-Phosphate Dehydrogenase (G6PD) in human blood.

CLINICAL SIGNIFICANCE

Glutathione(GSH) is the necessary condition of maintaining the stability of hemoglobin and the integrity of red cell membrane. Glutathione reductase itself needs sufficient amount of NADPH. The level of NADPH is kept sufficient by G6PD. G6PD deficiency can be triggered by some drugs, such as Antimalarial drugs, sulfone drugs, primaquine, sulfa drugs. Low G6PD values are found with G6PD deficiency, certain drugs, fava beans, infections, etc.

ASSAY PRINCIPLE

Glucose-6-phosphate dehydrogenase catalyzes the first step in the pentose phosphate shunt, oxidizing glucose-6-phosphate (G-6-P) to 6- phosphogluconate (6-PG) and reducing NADP to NADPH. Nictotinamide adenine dinucleotide phosphate (NADP) is reduced by G6PD in the presence of G-6-P. The rate of formation of NADPH is proportional to the G6PD activity and is measured colorimetrically as in increase in absorbance at 340nm. Involving the following reaction:

$$\text{G-6-P} + \text{NADP+} \xrightarrow[\text{Mg2+}]{\text{G6PDH}} \text{6-PG} + \text{NADPH} + \text{H+}$$

REAGENTCOMPOSITON

Contents	Concentration of Solutions
Reagent 1	
Tris-Hcl Buffer (PH8.00)	100mmol/L
Mgcl2	4mmol/L
NADP+	3mmol/L
Stabilizer	Appropriate
Preservative	Appropriate
Reagent 2	
Tris-Hcl Buffer (PH5.95)	100mmol/L
G6P	20mmol/L
Stabilizer	Appropriate
Preservative	Appropriate
Lyse Reagent	
Surfactant	Appropriate
Preservative	0.05%

SAMPLE COLLECTION AND PREPARATION

1. Venous blood or umbilical cord blood can be used for the assay
2. Whole blood collected in EDTA, heparin or Sodium citrate is satisfactory.
3. Red cell G6PD is stable in whole blood for one week refrigerated (2-8°C), but is unstable in red cell hemolysates
4. Jaundice, hemolysis, and chyle samples should be avoid.
5. PREPARATION OF SAMPLE: Anticoagulated whole blood sample should be centrifuged for 5 min at around 4000 rpm, then pipette 20 µl packed cell into 1 mL lys Reagent. Suspend the red cell hemolysates and then measured on the machine within 25 min.

STABILITY AND PREPARATION OF REAGENTS

The reagents and controls should be stored at 2-8° C. Do not freeze. The reagents and controls are stable when stored as instructed until the expiration date on the label. Please prevent cross-contamination if opened.

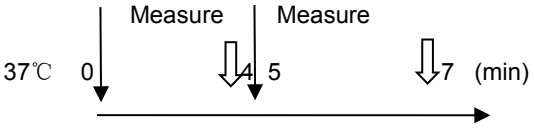
ASSAY PROCEDURE

Test Procedure for Analyzers (AU)

Assay Mode: Rate

Wave length (sub/main): 410/340nm

Sample:10 µl
R1: 180µl R2: 60 µl



CALIBRATION

K factor is recommended.

Beijing Strong Biotechnologies, Inc.
Add: 5/F,KuangYi Building,No.15,Hua Yuan Dong Lu,Haidian District,Beijing 100191,P.R.China
Tel: +86 10 8201 2486 Fax: +86 10 8201 2812

Web: www.bsbe.com.cn Email: jq.tech@bsbe.com.cn

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CALCULATION OF RESULTS

$$K=\frac{V_t \times 10^6}{\varepsilon \times L \times V_s}$$

G-6-PD (U/L) = ΔA/min × K×51

QUALITY CONTROL

Gcell G6PD Control (GQ-G6PD) is recommended as daily quality control sample. Please confirm the values should be within a specific range. If not, Please check:

1. The instrument settings and light source;
2. Reaction temperature;
3. Expiration date of kit and contents.

REFERENCE RANGE

Adult: 1300 - 3600 U/ L（1.30 -3.60 KU/L）
Child:1700 - 4000 U/ L（1.70 -4.00 KU/L）
Infant: 2500-5800U/L (2.50-5.80 KU/L）
It is recommended that each laboratory establish its own reference range to reflect the age, sex, diet and geographical location of the population.

SPECIFIC PERFORMANCE CHARACTERISTICS

LINEARITY

Linearity is 50～6000 U/L. Samples that exceeded the linearity limit (6000 U/L) should be diluted with an equal volume of water. Multiply the result by two.

PRECISION

The coefficient of variation (CV) for both Intra assay precision and Inter assay precision is below 10%

Intra assay precision		
N=20	Sample 1	Sample 2
Mean(U/L)	797.10	2714.5
SD	10.4	10.52
CV(%)	1.3%	0.39%

Inter assay precision			
N=5	Batch 1	Batch 2	Batch 3
Mean(U/L)	781.40	753.00	783.00
$\bar{x}$ (U/L)	772.47		
CV(%)=(Xmax-Xmin)/$\bar{x}$	3.75%		

SENSITIVITY

For analysis sensitivity, the absorbance change rate (**△A/min)** should be ≥0.0070 under the concentration of 2500 U/L.

CORRELATION

Tested the blood samples with Gcell G-6-PD assay kit (X) and a well-known brand kit (Y) at the same time. The correlation formula is Y=0.9897X- 56.045, R^2 = 0.9892

SAFETY PRECAUTIONS AND WARNINGS

1.For in vitro diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handling laboratory reagents.
2.Reagent contains Sodium Azide. Avoid ingestion or contact with skin or mucous membranes. In case of skin contact, flush affected area with copious amounts of water. In case of contact with eyes or if ingested, seek immediate medical attention.
3.Sodium Azide reacts with lead and copper plumbing, to form potentially explosive azides. When disposing of such reagents flush with large volumes of water to prevent azide from building up. Exposed metal surfaces should be cleaned with 10% sodium hydroxide.
4.Specimens should be treated as potentially infectious (HIV, Hepatitis B virus, Hepatitis C virus, etc.) and handled with appropriate caution.
5.Reagents with different lot numbers should not be interchanged or mixed.

REFERENCES

National Guide To Clinical Laboratory Procedures (Third Edition)

INDEX OF SYMBOLS

	Manufacture
REF	Catalogue Number
LOT	Lot number
	Date of manufacture
	Use by(Expiration date)
IVD	For In-Vitro Diagnostic use only
2℃ 8℃	Stored at 2-8℃
	Attention:See instruction for use
EC REP	Authorized Representative in the European Company

Manufacture：Beijing Strong Biotechnology, Inc.
Address： No. 15, Yanqi North Second Street, Yanqi Economic Development Area, Huairou District, Beijing 101400, P. R. China
Tel：+86 10 61667168

EC REP :Lotus NL B.V.
Address： Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.
E-mail：peter@lotusnl.com
Tel：+31645171879(English), +31626669008（Dutch）