



## GLU-OX Reagent Kit-2 (GOD-POD Method)

Instructions for Use

REF CC1040

### PRODUCT NAME

GLU-OX Reagent Kit-2 (GOD-POD Method)

### PACKAGE SPECIFICATION

R1: 1×20 mL	R2: 1×10 mL	R1: 1×40 mL	R2: 1×20 mL
R1: 1×60 mL	R2: 1×30 mL	R1: 2×60 mL	R2: 2×30 mL
R1: 2×30 mL	R2: 2×15 mL	R1: 2×40 mL	R2: 2×20 mL
R1: 2×50 mL	R2: 1×50 mL	R1: 2×60 mL	R2: 1×60 mL
R1: 2×60 mL	R2: 3×20 mL	R1: 2×65 mL	R2: 1×65 mL
R1: 2×65 mL	R2: 1×70 mL	R1: 2×80 mL	R2: 1×80 mL
R1: 2×120 mL	R2: 2×60 mL	R1: 3×20 mL	R2: 3×10 mL
R1: 3×40 mL	R2: 3×20 mL	R1: 4×40 mL	R2: 4×20 mL
R1: 4×50 mL	R2: 2×50 mL	R1: 4×55 mL	R2: 2×55 mL
R1: 4×60 mL	R2: 2×60 mL	R1: 4×60 mL	R2: 4×30 mL
R1: 4×60 mL	R2: 6×20 mL	R1: 4×65 mL	R2: 2×65 mL
R1: 4×65 mL	R2: 2×70 mL	R1: 4×100 mL	R2: 2×100 mL
12×72 T (R1: 12×16.8 mL R2: 12×8.4 mL)			
Calibrator (optional) 1×1 mL			

### INTENDED USE

Used for the *in vitro* quantitative determination of glucose concentration in human serum and plasma. Mainly used clinically to assess blood glucose levels. For professional and laboratory use only.

### TEST PRINCIPLE

$$\text{Glucose} + \text{O}_2 + \text{H}_2\text{O} \xrightarrow{\text{GOD}} \text{Gluconic acid} + \text{H}_2\text{O}_2$$

$$\text{H}_2\text{O}_2 + 4\text{-AAP} + \text{Phenol} \xrightarrow{\text{POD}} \text{Quinone imide} + 4\text{H}_2\text{O}$$
 By colorimetry at 505nm, GLU concentration can be calculated.

### MAIN COMPONENTS

Kit composition	Reagent components	Content
Reagent 1	Phosphate buffer(pH7.0)	10 g/L
	Phenol	2 g/L
Reagent 2	Glucose oxidase	40 KU/L
	Peroxidase	3 KU/L
	4-Aminoantipyrine	0.3 g/L
Calibrator (optional)	glucose, aqueous matrix	5-6 mmol/L

The components in different batches of a multi-component kit are not interchangeable. Calibrator traceability: traceable to National Reference Material GBW(E)090544.

### STORAGE AND SHELF LIFE

Unopened reagents should be stored at 2°C-8°C away from light, with a shelf life of 18 months. Opened reagents are stable for 42 days when stored at 2°C-8°C. Please refer to the label on the reagent kit for the production date and expiration date.

### APPLICABLE INSTRUMENTS

The kit is applicable to the following instruments: fully automatic biochemistry analyzers from Hitachi High-Tech (Shanghai) International Trading Co., Ltd., models: 7100, 7180, 7600, LABOSPECT 008 AS, 3100, 3500; fully automatic biochemistry analyzers from Beckman Coulter Commercial Enterprise (China) Co., Ltd., models: DXC800, AU480, AU680, AU5800; fully automatic biochemistry analyzers from Canon Medical Systems (China) Co., Ltd., models: TBA-120FR, TBA-2000FR, TBA-FX8; fully automatic biochemistry analyzers from Shenzhen Mindray Bio-Medical Electronics Co., Ltd., models: BS-420, BS-490, BS-600, BS-800, BS-820, BS-2000; fully automatic biochemistry analyzers from Dirui Industrial Co., Ltd., models: CS-400, CS-600B, CS-1200; fully automatic biochemistry analyzers from Siemens Healthineers Diagnostics (Shanghai) Co. Ltd., models: 1800, 2400, ADVIA Chemistry XPT; fully automatic biochemistry analyzers from Roche Diagnostics (shanghai) Co., Ltd., models: cobas 6000 c 501, cobas 8000 c 502, 701, 702; clinical chemistry analyzers from Getein Biotech, Inc, models: CM-400, CM-430, CM-480, CM-600, CM-630, CM-680, CM-800, CM-830, CM-880, CM-2000, CM-1600, CM-1200, CM-1000; automatic biochemistry analyzers from Changchun Blaser Medical Technology Co., LTD, models: BBA-400, BBA-300, BBA-480. If you need the application parameters of the fully automatic biochemistry analyzers, please contact our company.

### SAMPLE REQUIREMENTS

The anticoagulant plasma with potassium oxalate and sodium chloride is preferable, which can inhibit glucose decomposition. The test results for serum and plasma will not change within 7 days at 15-25°C, 7 days at 2-8°C and 1 year at -20°C.

### TEST PROCEDURE

1. Reagent preparation: Dual reagents are ready-to-use without reconstitution.
2. Test conditions: (Different load parameters can be requested based on different testing instruments)

Primary/secondary wavelength	505 nm/600 nm	Calibration type	Linearity
Sample/R1/R2	3/200/100 µL	Time of mixture of serum + R1	1-5 min
Method	Two-point end point assay	Reaction time after addition of R2	5 min
Calibration method	Two-point calibration	Direction of reaction	Upward

Operating procedures:  
Dual Reagent Operation

Sample	3 µL
Reagent 1 (R1)	200 µL
Mix well, incubate at 37°C for 1-5 min	
Reagent 2 (R2)	100 µL
Mix well, incubate at 37°C for 8 min, and then read the absorbance A.	

3. Calibration procedure: A calibrator from Getein is recommended, and a calibration serum from Randox can also be used.
4. Quality control procedure: select quality control serum from Randox, and its measured value should be within the range of its label claimed. If the result deviates from the range, find out the reason according to the steps below:
  - 4.1 Check whether the parameter settings and light source are correct.
  - 4.2 Check whether the cuvettes and sampling probes are clean.
  - 4.3 Check whether water is contaminated, and bacterial growth will cause incorrect results.
  - 4.4 Check reaction temperature.
  - 4.5 Check the expiration date of the kit.
5. Result calculation

$$\text{GLU concentration (mmol/L)} = \text{Concentration of GLU Standard Reference Material (SRM)} \times \frac{\Delta A_{\text{test sample}}}{\Delta A_{\text{SRM}}}$$

### REFERENCE RANGE

Reference range: 3.89-6.11 mmol/L (70-110 mg/dL)

The reference range is for reference only. It is recommended that each laboratory should establish its own reference range.

### RESULT INTERPRETATION

Sample with haemolysis interferes the measurement of this assay and should be avoided as much as possible during the procedure. Sample storage time also has an effect on the assay.

## LIMITATIONS

There is no interference with measurement when hemoglobin  $\leq 200$  mg/dL, ascorbic acid  $\leq 5$  mg/dL, bilirubin  $\leq 20$  mg/dL and triglycerides  $\leq 500$  mg/dL.

## PERFORMANCE CHARACTERISTICS

### 1. Appearance

Reagent 1 in the kit is a colorless or slightly yellow clear liquid, which may contain a small number of subvisible particles that do not affect determination. Reagent 2 is a yellow clear liquid, which may contain a small number of subvisible particles that do not affect determination.

### 2. Reagent blank absorbance

Reagent blank absorbance  $A_{505nm} \leq 0.200$ .

### 3. Accuracy

When the concentration  $\leq 4.16$  mmol/L, the deviation between the actual value and the indicated value should not exceed  $\pm 0.833$  mmol/L. When the concentration  $> 4.16$  mmol/L, the relative deviation should not fall outside the range of  $\pm 20\%$ .

### 4. Linear range

Reagent linearity: [0.3, 25] mmol/L

a) The linear correlation coefficient (r) should not be less than 0.9900;

b) The deviation from linearity should not fall outside the range of  $\pm 0.2$  mmol/L for testing within the linear range of [0.3, 1] mmol/L; the deviation from linearity should not fall outside the range of  $\pm 10\%$  for testing within the linear range of (1, 25] mmol/L.

### 5. Analytical sensitivity

When a sample has a concentration of 0.5 mmol/L, its absorbance difference should be  $\leq 0.037$ .

### 6. Precision

#### 6.1 Within-run precision

Within-run precision should not be more than 5.0%.

#### 6.2 Between-run precision

Between-run precision should not be more than 10.0%.

## PRECAUTIONS

### 1. General precautions

1.1 This product is for *in vitro* diagnostic use only.

1.2 For clinical diagnosis, please make a comprehensive judgment based on the measurements, clinical symptoms and other findings.

1.3 Please use this product according to the IFU.

### 2. Precautions for operation

2.1 Please treat the specimens as dangerous substances that may be infected with HIV, HBV, HCV, etc. Please use disposable gloves to avoid or reduce the associated risk for infection.

2.2 If the reagents get into the eyes or mouth, or come into contact with the skin, rinse them quickly and thoroughly with water, and receive medical treatment from a doctor when necessary.

### 3. Precautions for use

3.1 Please store the reagents according to the storage method, and avoid freezing. Please do not use frozen reagents whose quality may change.

3.2 Please do not use expired reagents whose test results may be inaccurate.

3.3 Please avoid adding reagents halfway during a test.

3.4 Please avoid direct sunlight during operation.

3.5 Do not use the reagents with visible signs of turbidity.

### 4. Precautions for waste disposal

Samples, waste liquids, etc. are potentially biologically contaminated. Operators should comply with the SOP for laboratory safety and dispose of waste liquids in accordance with local regulations for medical waste, infectious waste, industrial waste, etc.

### 5. Other precautions

5.1 On a fully automatic biochemistry analyzer, the linearity range is related to the ratio of the amount of a sample to the amount of a reagent and the time of measurement.

5.2 The amounts of the reagent and sample can be changed proportionally according to the requirements of different instruments.

5.3 Please do not use the reagent bottles for other purposes.

5.4 A result calculated with the k value is not as reliable as that obtained using the SRM (calibrator).
















5.5 Please do not mix reagents in different batches.

## REFERENCE

Shang Hong et al. National clinical testing operation procedures (4<sup>th</sup> ed.). People's Health Publishing House.2015:230-233.

## DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on GLU-OX Reagent Kit-2 (GOD-POD Method) are the most common ones appearing on medical devices and their packaging. They are explained in more details in the European Standard EN ISO 15223-1:2021.

Key to symbols used					
	Manufacturer		Use-by date		Catalogue number
	Date of manufacture		Batch code		Temperature limit
	<i>In vitro</i> diagnostic medical device		Keep away from sunlight		Biological risks
	Consult <i>instructions for use</i> or consult <i>electronic instructions for use</i>		Do not use if package is damaged and consult <i>instructions for use</i>		Authorized representative
	CE mark		This way up		Do not re-use



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