ELK Biotechnology

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Glucose Assay Kit (Glucose Oxidase Method) Instructions

Catalog number:BC014 Size:4×50ml

【Product Name】

Common name: Glucose determination kit (glucose oxidase method)

【Reagent Specification】

	Size
Reagent	4×50mL
Calibrator	1×1mL

【Intended usage】

This product is used by medical institutions for in vitro detection of glucose concentration in serum or plasma to assist diagnosis.

Accurate measurement of glucose is very important for diagnosing hyperglycemia. Often when searching for the cause of these conditions, various tolerance and inhibition tests are performed along with glucose measurements. Increased glucose levels are seen in: diabetes, excessive glucose intake, Cushing's syndrome, and cerebrovascular accidents. Decreased glucose levels are seen in: Isletoma, Insulin overdose, and congenital disorders of carbohydrate metabolism.

【Testing Principle】

Glucose in the sample is generated by glucose oxidase to form gluconic acid and hydrogen peroxide, which, under the action of peroxidase, condenses reduced 4-aminoantipyrine with phenol and synthesizes quinone compounds that can be measured spectrophotometrically.

【Main ingredients】

	Element	Concentration
Reagent	Glucose Oxidase	36 ku/L
	Peroxidase	1ku/L
	Phosphate Buffer	pH7.0
	Phenol	1ml/L
	4-Aminoantipyrine	0.102 g/L
Calibrator	Benzoic Acid	Adequate
	Glucose	1.099g/L

Note: The theoretical concentration of the calibrator is 5.55mmol/L, which is traceable to NIST SRM917b/NIST SRM 965a. Components in kits from different batch numbers are not interchangeable.

【Storage conditions and validity period】

Reagents and calibrators should be protected from light and stored at 2 to 8°C for 12 months from the date of production. The production date and expiration date are on the label.

【Applicable instruments】

This product is primarily intended for use on the following open-ended semi-automated biochemistry analyzers. It is recommended that the user validate this product in the laboratory before using it on the following instruments:

2000Ⅲ, Kate NB-201, Matsunami A6, Gao Mi GF-D600/800, Ai Wei AVE-854, Sanomaid SBA-830, Rittal vital Microlab 300, TRACE CB171.

【Sample requirement】

Serum or plasma should be separated from the sample tube as quickly as possible and should not be hemolyzed. Glucose in serum or plasma can be stored for 24 hours at 2~8℃.

【Testing method】

1.Reagent preparation: This reagent is used directly.

2.Experimental condition:

Temperature	37℃	Sample volume	10μL
Wavelength	505nm	Reagent consumption	1000μL
Reaction time	10 minutes	Measured optical diameter	1.0cm

Measurement Mode	Endpoint method		

3.Calibration and quality control procedures：

	Sample tube	Calibration tube	Quality control tube	Blank tube
Sample (μL)	10	——	——	——
Calibration solution(μL)	——	10	——	——
Quality control solution (μL)	——	——	10	——
Distilled water (μL)	——	——	——	10
Glucose reagent (μL)	1000	1000	1000	1000

Set at 37℃ for 10 minutes, use the wavelength of 505nm, colorimetric cup optical diameter of 1.0 cm, with a blank tube to adjust the "zero" point to determine the absorbance (A) value of each tube. The samples must be calibrated with a traceable calibrator and then tested with a commercial, traceable quality control product, and the results must be within the allowable range before the samples are tested.

4. Calculation of test results

$$\text{Glucose(mmol/L)} = \frac{\text{Absorbance of sample tubes(A)}}{\text{Absorbance of Calibration Tube(A)}} \times \text{Standard solution concentration}$$

Glucose(mg/dL)=mmol/L×18

Note: Depending on the instrument used, the amounts of reagents and samples can be changed in a constant ratio.

【Reference interval】

Serum/plasma: 3.89~6.11 mmol/L (70~110 mg/dL).

The quoted reference range represents the expected value of the method and is for reference only. It is recommended that laboratories validate this reference range or establish their own reference range.

【Interpretation of test results】

Bilirubin ≤684 μmolL, hemoglobin ≤4 g/L, vitamin C ≤0.4 g/L, and triglycerides ≤5.0 mmo/L did not interfere with the results.

【Limitations of the test method】

When the test result is greater than 28 mmol/L, please dilute with saline before measurement and multiply the result by the dilution factor.

【Product Performance Indicators】

1.Appearance: the reagent is colorless to light yellow clarified liquid.

2.Net content: reagent content ≥ labeled amount.

3.Absorbance of reagent blank: ≤0.20A (wavelength 505nm, optical diameter 1.0cm).

4.Analytical sensitivity: When the reagent tests 5.55mmol/L GLU samples, the difference of absorbance change (△A) ≥0.15A.

5.Reagent linear range: reagent in the (1.4 ~ 28) mmol / L linear range, analytical performance should meet the following requirements:

a) linear correlation coefficient r ≥ 0.990.

b) Linear deviation does not exceed ±15%.

6.Measurement precision:

6.1 Repeatability: the repeatability (coefficient of variation, CV) of the results obtained by repeated testing with control serum should be ≤5.0%.

6.2 Inter-batch difference: the difference between batches of reagents should be ≤5.0%.

7. Accuracy: The accuracy of the reagents for the determination of certified reference substances should be ≤ ± 10% (relative deviation method) or the results of the determination of special quality control products within the permissible range.

8. Stability:

Validity stability: the kit can be stable for twelve months since the production date, stored at 2-8 ℃ away from light, take the sample near the validity period of the reagent blank absorbance, analytical sensitivity, linear range, repeatability, accuracy, should be in line with the requirements of the 3,4,5,6.1,7, respectively.

9. Appearance of the calibrator: the calibrator should be a colorless, clarified liquid.

10. Calibration product loading: the content of calibration product is not less than the labeled amount.

11.Accuracy of the calibrators: the calibrators are calibrated by third party certified calibrators, and the relative deviation of the calibrators in the test kit from the indicated value of the calibrators is not more than ±10%.

12. Repeatability of calibrators: the repeatability (coefficient of variation, CV) of calibrators within the bottle should b

e ≤5.0%.

13. Uniformity of calibrators: inter-bottle reproducibility (coefficient of variation, CV) of calibrators should be ≤5.0%.

14. Stability of calibrators:

14.1 potency stability: store the calibration products from the production date at 2-8 ℃ to near the end of the potency period, the accuracy of detection, the results should meet the requirements of 11.

14.2.Open cap stability: place the calibration products after opening the lid at 2-8 ℃ in 10 days after the test, the results should meet the requirements of 11.

【Precautions】

1.The kit is for in vitro diagnostic use only.

2.The reagent contains preservatives and stabilizers, which may have certain irritating effect or toxicity, please do not contact with skin and eyes directly. Once contacted, flush with plenty of water. Do not swallow.

3.The dosage of reagents and samples can be changed proportionally.

4.After drawing blood, serum or plasma should be separated from the red blood cells quickly to avoid glycolysis. If sodium fluoride is added, fermentation can be prevented within 24 hours.

5. To ensure accurate and reliable test results, quality control must be performed for each batch of determination.