GENLISA® Blood Glucose Assay

REF : KBCA1216

Ver 1.0

RUO

Biochemical Assay for the Quantitative Determination of Blood Glucose in serum, plasma tissue cells, cell culture supernatants and other biological samples

RUO	For Research Use Only	REF	Catalog Number
	Store At	LOT	Batch Code
	Manufactured By		Biological Risk
	Expiry Date		Consult Operating Instructions

REF KBCA1216 Σ 50 tests

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GENLISA® Blood Glucose Assay

Introduction:

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.

Intended Use:

The GENLISA® Blood Glucose Assay kit is used as an analytical tool for quantitative determination of Blood Glucose in serum, plasma, tissue cells, cell culture supernatants and other biological samples.

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.

Materials Provided:

1. Reagent – 4 x 50 ml
2. Calibrator – 1 x 1 ml

Main Ingredients:

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

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

Materials to be provided by the End-User:

1. Microtiter Plate Reader able to measure absorbance at 450 nm.
2. Adjustable pipettes and multichannel pipettor to measure volumes ranging from 25 ul to 1000 ul.
3. Deionized (DI) water.
4. Wash bottle or automated microplate washer.
5. Clean tubes and Eppendorf tubes.
6. Precision single and multi-channel pipette and disposable tips.

Handling/Storage:

1. All reagents should be stored as indicated on the component label and keep away from the light.
2. Standard should be stored at 2-8°C.
3. All the reagents should be used within 12 months from manufacturing date.
4. Before using, bring all components to 2-8ºC. Upon assay completion ensure all components of the kit are returned to appropriate storage conditions.

Health Hazard Warnings:

1. Reagents that contain preservatives may be harmful if ingested, inhaled or absorbed through the skin.
2. For Research Use Only.

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:

2000 III, Kate NB-201, Matsunami A6, Gao Mi GF-D600/800, Ai Wei AVE-854, Sanomaid SBA-830, Rittal vital Microlab 300, TRACE CB171.

Sample Preparation:

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 2~8ºC.

Testing Method:

1. **Reagent preparation:** This reagent is used directly.

2. **Experimental Condition:**

Temperature	37ºC	Sample Volume	10 ul
Wavelength	505nm	Reagent Consumption	1000 ul
Reaction Time	10 minutes	Measured optical diameter	1.0 cm
Measurement Mode	Endpoint Method		

3. **Calibration and quality control procedures:**

	Sample Tube	Calibration Tube	Quality Control Tube	Blank Tube
Sample (ul)	10	-	-	-
Calibration Solution (ul)	-	10	-	-
Quality Control Solution (ul)	-	-	10	-
Distilled Water (ul)	-	-	-	10
Glucose Reagent (ul)	1000	1000	1000	1000

Set at 37ºC for 10 minutes, use the wavelength of 505 nm, 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 samplesare tested.

Calculation of Results:

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

Glucose (mg/dl) = mmol/l x 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 recommende d that laboratories validate this reference range or establish their own reference range.

Interpretation of Results:

Bilirubin ≤ 684 umol/l, 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.

Performance Characteristics of the Kit:

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 5.55 mmol/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 follow ing 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^{0}C 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 be ≤ 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- 8^0Cto 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- 8^0Cin 10 days after the test, the results should meet the requirements of 11.

Safety Precautions:

- **This kit is For Research Use only**. Follow the working instructions carefully.
- The expiration dates stated on the kit are to be observed. The same relates to the stability stated for reagents.
- Do not use or mix reagents from different lots.
- Do not use reagents from other manufacturers.
- Avoid time shift during pipetting of reagents.
- All reagents should be kept in the original shipping container.
- Some of the reagents contain small amount of sodium azide (< 0.1 % w/w) as preservative. They must not be swallowed or allowed to come into contact with skin or mucosa.
- Source materials maybe derived from body fluids or organs used in the preparation of this kit were tested and found negative for HBsAg and HIV as well as for HCV antibodies. However, no known test guarantees the absence of such viral agents. Therefore, handle all components and all patient samples as if potentially hazardous.
- Since the kit contains potentially hazardous materials, the following precautions should be observed.
- Do not smoke, eat or drink while handling kit material.
- Always use protective gloves.
- Never pipette material by mouth.
- Wipe up spills promptly, washing the affected surface thoroughly with a decontaminant.
- In any case GLP should be applied with all general and individual regulations to the use of this kit.

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