respons®920

# Glucose Hexokinase FS*

## Order Information

| Cat. No. | Kit size |
|---|---|
| 1 2511 99 10 920 | Σ 800 (4 x 200) |

## Intended Use

Diagnostic reagent for quantitative in vitro determination of glucose in human serum, heparin plasma or urine on automated respons®920.

## Summary

Glucose is a monosaccharide and one of the most important carbohydrates for the human organism, as it is a metabolic substrate and a source of energy. The glucose concentration in blood is kept constant by several regulatory mechanisms. The main regulation occurs via secretion of insulin and glucagon. Primarily for the organism, the coverage of the steady glucose demand of the central nervous system with only minimal glucose reserves and the demand of erythrocytes is of major importance [1]. Glucose concentration in blood depends on nutritional status of an individual. Three conditions can be distinguished: Fasting status (8-10 h after the last nutritional intake), postprandial status (2-3 h after beginning of food intake) and postabsorptive status (6-12 h after beginning of food intake) [2]. Glucose measurement is recommended, whenever hypo- or hyperglycemia is suspected. Altered glucose can be the cause of many medical conditions. The main diseases causing elevated blood glucose levels are the different types of diabetes mellitus (DM). The primary purpose of glucose measurement is to diagnose DM respectively to define and monitor therapeutic interventions [2].

## Method

Enzymatic UV test using hexokinase

Glucose is phosphorylated by hexokinase in the presence of ATP to form glucose-6-phosphate. Glucose-6-phosphate is converted in presence of $NAD^+$ by glucose-6-phosphate dehydrogenase to gluconate-6-phosphate and NADH + $H^+$. The increase of absorbance of NADH + $H^+$ is determined spectrophotometrically at a wavelength of 340 nm as endpoint measurement. The increase of absorbance is proportional to the glucose concentration in the sample.

$$\text{Glucose} + \text{ATP} \xrightarrow{\text{HK}} \text{Glucose-6-phosphate} + \text{ADP}$$

$$\text{Glucose-6-phosphate} + \text{NAD}^+ \xrightarrow{\text{G6P-DH}} \text{Gluconate-6-phosphate} + \text{NADH} + \text{H}^+$$

## Reagents

**Components and Concentrations**

| | | | |
|---|---|---|---|
| **R1:** | TRIS buffer | pH 7.8 | 100 mmol/L |
| | $Mg^{2+}$ | | 4 mmol/L |
| | ATP | | 2.1 mmol/L |
| | NAD | | 2.1 mmol/L |
| **R2:** | $Mg^{2+}$ | | 4 mmol/L |
| | Hexokinase | (HK) | ≥ 7.5 kU/L |
| | Glucose-6-phosphate dehydrogenase | (G6P-DH) | ≥ 7.5 kU/L |

## Storage and Stability

Reagents are stable up to the date of expiry indicated on the kit, if stored at 2 – 8°C and contamination is avoided. Do not freeze and protect from light.

The open-vial stability of the reagent is 12 months until expiry date.

## Warnings and Precautions

1. The reagents contain sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.
2. Reagent 2 contains material of biological origin. Handle the product as potentially infectious according to universal precautions and good clinical laboratory practice.
3. To avoid carryover interference, please take care of efficient washing especially after use of interfering reagents. Please refer to the DiaSys respons®920 Carryover Pair Table. Carryover pairs and automated washing steps with the recommended cleaning solution can be specified in the system software. Please refer to the user manual.
4. In very rare cases, samples of patients with gammopathy might give falsified results [3].
5. In case of product malfunction or altered appearance that could affect the performance, contact the manufacturer.
6. Any serious incident related to the product must be reported to the manufacturer and the competent authority of the Member State where the user and/or patient is located.
7. Please refer to the safety data sheets (SDS) and take the necessary precautions for the use of laboratory reagents. For diagnostic purposes, the results should always be assessed with the patient's medical history, clinical examinations and other findings.
8. For professional use only.

## Waste Management

Refer to local legal requirements for chemical disposal regulations as stated in the relevant SDS to determine the safe disposal.

Warning: Handle waste as potentially biohazardous material. Dispose of waste according to accepted laboratory instructions and procedures.

## Reagent Preparation

The reagents are ready to use. The bottles are placed directly into the reagent rotor.

## Materials Required

General laboratory equipment

## Specimen

Human serum, heparin plasma or urine

Only use suitable tubes or collection containers for specimen collection and preparation.

When using primary tubes, follow the manufacturer's instructions.

Separate at the latest 1h after blood collection from cellular contents.

Stability in serum/plasma after addition of a glycolytic inhibitor (fluoride, monoiodacetate, mannose) [4]:

| | | |
|---|---|---|
| 2 days | at | 20 – 25°C |
| 7 days | at | 4 – 8°C |
| 1 day | at | -20°C |

Only freeze once. Discard contaminated specimens.

Stability in serum (separated from cellular contents, hemolysis free) without adding a glycolytic inhibitor [5,6]:

| | | |
|---|---|---|
| 8 h | at | 25°C |
| 72 h | at | 4°C |

Discard contaminated specimens.

Stability in urine [4]:

| | | |
|---|---|---|
| 2 h | at | 20 – 25°C |
| 2 h | at | 4 – 8°C |
| 2 days | at | -20°C |

Only freeze once. Discard contaminated specimens.

## Calibrators and Controls

DiaSys TruCal U is recommended for calibration. Calibrator values have been made traceable to the reference method gas chromatography – isotope dilution mass spectrometry (GC-IDMS). Use DiaSys TruLab N and P or TruLab Urine Level 1 and Level 2 for internal quality control. All target values of the controls are traceable to DiaSys reagent/calibrator system. Quality control must be performed after calibration. Control intervals and limits have to be adapted to the individual requirements of each laboratory. Results must be within the defined ranges. Follow the relevant legal requirements and guidelines. Each laboratory should establish corrective action in case of deviations in control recovery.

| | Cat. No. | Kit size |
|---|---|---|
| TruCal U | 5 9100 99 10 063 | 20 x 3 mL |
| | 5 9100 99 10 064 | 6 x 3 mL |
| TruLab N | 5 9000 99 10 062 | 20 x 5 mL |
| | 5 9000 99 10 061 | 6 x 5 mL |
| TruLab P | 5 9050 99 10 062 | 20 x 5 mL |
| | 5 9050 99 10 061 | 6 x 5 mL |
| TruLab Urine Level 1 | 5 9170 99 10 062 | 20 x 5 mL |
| | 5 9170 99 10 061 | 6 x 5 mL |
| TruLab Urine Level 2 | 5 9180 99 10 062 | 20 x 5 mL |
| | 5 9180 99 10 061 | 6 x 5 mL |

## Performance Characteristics

**Serum/Plasma**

| Measuring range up to 1000 mg/dL, linearity is given within ± 5%. In case of higher concentrations re-measure samples after manual dilution with NaCl solution (9 g/L) or use rerun function. | |
|---|---|
| Limit of detection** | 0.3 mg/dL |
| Onboard stability | 4 weeks |
| Calibration stability | 4 weeks |

| Interference by | Interferences ≤ 10% up to | Analyte concentration [mg/dL] |
|---|---|---|
| **Ascorbic acid** | 30 mg/dL | 179 |
| **Bilirubin** (conjugated) | 60 mg/dL | 168 |
| **Bilirubin** (unconjugated) | 60 mg/dL | 171 |
| **Hemolysis** | 1000 mg/dL | 83.7 |
| **Lipemia** (triglycerides) | 2000 mg/dL | 81.4 |

For further information on interfering substances, refer to the literature [7-9].

| **Precision** | | | |
|---|---|---|---|
| **Repeatability (n=20)** | **Sample 1** | **Sample 2** | **Sample 3** |
| Mean [mg/dL] | 92.9 | 132 | 291 |
| CV [%] | 0.852 | 1.25 | 1.95 |
| **Between day (n=20)** | **Sample 1** | **Sample 2** | **Sample 3** |
| Mean [mg/dL] | 89.8 | 127 | 284 |
| CV [%] | 1.62 | 1.61 | 1.41 |

| **Method comparison (n=99)** | |
|---|---|
| Test x | DiaSys Glucose Hexokinase FS (Hitachi 911) |
| Test y | DiaSys Glucose Hexokinase FS (respons®920) |
| Slope | 1.02 |
| Intercept | 0.321 mg/dL |
| Coefficient of correlation | 0.999 |

**Urine**

| Measuring range up to 1000 mg/dL, linearity is given within ± 5%. In case of higher concentrations re-measure samples after manual dilution with NaCl solution (9 g/L) or use rerun function. | |
|---|---|
| Limit of detection** | 0.3 mg/dL |
| Onboard stability | 4 weeks |
| Calibration stability | 4 weeks |

| **Precision** | | | |
|---|---|---|---|
| **Repeatability (n=20)** | **Sample 1** | **Sample 2** | **Sample 3** |
| Mean [mg/dL] | 9.94 | 26.4 | 284 |
| CV [%] | 0.971 | 0.608 | 0.972 |
| **Between day (n=20)** | **Sample 1** | **Sample 2** | **Sample 3** |
| Mean [mg/dL] | 9.87 | 25.0 | 270 |
| CV [%] | 5.16 | 1.74 | 1.71 |

| **Method comparison (n=98)** | |
|---|---|
| Test x | DiaSys Glucose Hexokinase FS (BioMajesty® JCA-BM6010/C) |
| Test y | DiaSys Glucose Hexokinase FS (respons®920) |
| Slope | 0.999 |
| Intercept | -0.191 mg/dL |
| Coefficient of correlation | 0.998 |

** lowest measurable concentration which can be distinguished from zero; mean + 3 SD (n = 20) of an analyte free specimen.

**Conversion Factor**

Glucose [mg/dL] x 0.05551 = Glucose [mmol/L]

## Reference Range

| | [mg/dL] | [mmol/L] |
|---|---|---|
| **Newborns** | | |
| Cord blood | 63 – 158 | 3.5 – 8.8 |
| 1 h | 36 – 99 | 2.0 – 5.5 |
| 2 h | 39 – 89 | 2.2 – 4.9 |
| 5 – 14 h | 34 – 77 | 1.9 – 4.3 |
| 20 – 28 h | 46 – 81 | 2.6 – 4.5 |
| 44 – 52 h | 48 – 79 | 2.7 – 4.4 |
| **Children (fasting)** | 60 – 99 | 3.3 – 5.5 |
| **Adults (fasting)** | | |
| Serum/Plasma | 60 – 95 | 3.3 – 5.3 |
| Urine | ≤ 16.5 | ≤ 0.91 |

Each laboratory should check if the reference ranges are transferable to its own patient population and determine own reference ranges if necessary.

## Literature


1. Hallbach J. Klinische Chemie und Hämatologie – Biomedizinische Analytik für MTLA und Studium. 3rd ed. Stuttgart: Georg Thieme Verlag KG; 2011. p. 170-171.
2. Thomas L. Clinical Laboratory Diagnostics [Internet]. Prof. Lothar Thomas; 2020 [cited 2024 Mar 27]. Available from: https://www.clinical-laboratory-diagnostics.com/
3. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: mechanisms, detection and prevention. ClinChemLabMed 2007;45(9):1240-1243.
4. Guder WG et al. Die Qualität diagnostischer Proben – Empfehlung der Arbeitsgruppe Präanalytik der Deutschen Vereinten Gesellschaft für Klinische Chemie und Laboratoriumsmedizin. 7th ed. Heidelberg: BD Diagnostics Preanalytical Systems; 2012. p. 46-47, p. 68-69.
5. Sacks DB. Carbohydrates. In: Burtis CA, Ashwood ER, Bruns DE, editors. Tietz Textbook of Clinical Chemistry and Molecular Diagnosis. 4th ed. St. Louis, Missouri: Elsevier Saunders Company; 2006. p. 837-901.
6. Sacks DB, Bruns DE, Goldstein DE, MacLaren NK, McDonald JM, Parrott M. Guidelines and Recommendations for Laboratory Analysis in the Diagnosis and Management of Diabetes Mellitus. ClinChem 2002; 48: 436-472.
7. Young DS. Effects of Drugs on Clinical Laboratory Tests. 5th ed. Volume 1 and 2. Washington, DC: The American Association for Clinical Chemistry Press 2000.
8. Young DS. Effects on Clinical Laboratory Tests - Drugs Disease, Herbs & Natural Products, https://clinfx.wiley.com/

aaccweb/aacc/, accessed in February 2024. Published by AACC Press and John Wiley and Sons, Inc.
9. Sonntag O, Scholer A. Drug interference in clinical chemistry: recommendation of drugs and their concentrations to be used in drug interference studies. Ann Clin Biochem. 2001 Jul;38:376-85.

Additions and/or changes in the document are highlighted in grey. Deletions are communicated via customer info by stating the edition no. of the package insert/instruction for use.

IVD CE

DiaSys Diagnostic Systems GmbH
Alte Strasse 9 65558 Holzheim
Germany
www.diasys-diagnostics.com

* Fluid Stable

respons®920

# Glucose Hexokinase FS

## Application for serum, plasma or urine

| Test Details | | | Test Volumes | | | Reference Ranges | | |
|---|---|---|---|---|---|---|---|---|
| Test | : | GLUHK | | | | Auto Rerun | ☐ | |
| Report Name | : | Glucose Hexokinase | | | | Online Calibration | ☐ | |
| Unit | : | mg/dL | Decimal Places | : | 1 | Cuvette Wash | ☐ | |
| Wavelength-Primary | : | 340 | Secondary | : | 405 | Total Reagents | : | 2 |
| Assay Type | : | 2-Point | Curve Type | : | Linear | Reagent R1 | : | GLUHK R1 |
| M1 Start | : | 15 | M1 End | : | 15 | Reagent R2 | : | GLUHK R2 |
| M2 Start | : | 33 | M2 End | : | 33 | | | |
| Sample Replicates | : | 1 | Standard Replicates | : | 3 | **Consumables/Calibrators:** | | |
| Control Replicates | : | 1 | Control Interval | : | 0 | Blank /Level 0 | | 0 |
| Reaction Direction | : | Increasing | React. Abs. Limit | : | 0.0000 | Calibrator 1 | | * |
| Prozone Limit % | : | 0 | Prozone Check | : | Lower | | | |
| Linearity Limit % | : | 0 | Delta Abs./Min. | : | 0.0000 | | | |
| Technical Minimum | : | 0.3000 | Technical Maximum | : | 1000.0000 | | | |
| Y = aX + b a= | : | 1.0000 | b= | : | 0.0000 | | | |

* Enter calibrator value.

| Test Details | | | Test Volumes | Reference Ranges |
|---|---|---|---|---|
| Test | : | GLUHK | | |
| Sample Type | : | Plasma/serum/ urine | | |

**Sample Volumes**

| | | | | | | |
|---|---|---|---|---|---|---|
| Normal | : | 4.00 | µL | Dilution Ratio | : | 1 X |
| Increase | : | 6.00 | µL | Dilution Ratio | : | 1 X |
| Decrease | : | 2.00 | µL | Dilution Ratio | : | 1 X |
| Standard Volume | : | 4.00 | µL | | | |

**Reagent Volumes and Stirrer Speed**

| | | | | | | |
|---|---|---|---|---|---|---|
| RGT-1 Volume | : | 180 | µL | R1 Stirrer Speed | : | High |
| RGT-2 Volume | : | 45 | µL | R2 Stirrer Speed | : | High |

**Sample Types**

- ☑ Serum
- ☑ Urine
- ☐ CSF
- ☑ Plasma
- ☐ Whole Blood
- ☐ Other

| Test Details | | | Test Volumes | Reference Ranges |
|---|---|---|---|---|
| Test | : | GLUHK | | |
| Sample Type | : | Plasma | | |
| Reference Range | : | DEFAULT | | |
| Category | : | Male | | |

**Reference Range**

| | | Lower Limit (mg/dL) | Upper Limit (mg/dL) |
|---|---|---|---|
| Normal | : | 70.00 | 115.00 |
| Panic | : | 0.00 | 0.00 |

**Sample Types**

- ☑ Serum
- ☑ Urine
- ☐ CSF
- ☑ Plasma
- ☐ Whole Blood
- ☐ Other