

Glucose/Hemoglobin IS*

Diagnostic reagent for quantitative in vitro determination of glucose and total hemoglobin in whole blood on InnovaStar®

Order Information

Cat. No.	
1 2491 99 10 760	100 determinations
970 100	InnovaStar® (instrument)
970 113	10 x 100
	Sample Cups InnovaStar® 10/500
920 709	10 x 100
	Open-end capillaries 10 µL (heparinized)
970 115	300 mL System solution InnovaStar®

Reagents

Components and Concentrations

Reagent:

R1:	Phosphate buffer	pH 7.5	250 mmol/L
	Trinder component		0.5 mmol/L
R2:	4-Aminoantipyrine		10 mmol/L
	Glucose oxidase	(GOD)	≥ 150 kU/L
	Peroxidase	(POD)	≥ 10 kU/L

Storage Instructions and Reagent Stability

The reagent is stable up to the end of the indicated month of expiry, if stored at 2 – 8°C and protected from light. Do not freeze reagents! Damaged or opened reagent cartridges must not be used!

Waste Management

Please refer to local legal requirements.

Reagent Preparation

The reagent is ready to use.

Bring reagent to room temperature. Make sure that the reagent is at the bottom of the cartridge.

Literature

1. Thomas L. Clinical Laboratory Diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 131-7.
2. Sacks DB. Carbohydrates. In: Burtis CA, Ashwood ER, editors. Tietz Textbook of Clinical Chemistry. 3rd ed. Philadelphia: W.B Saunders Company; 1999. p. 750-808.
3. Sacks DB, Bruns DE, Goldstein DE, Mac Laren NK, McDonald JM, Parrott M. Guidelines and recommendations for laboratory analysis in the diagnosis and management of diabetes mellitus. Clin Chem 2002; 48: 436-72.
4. Data on file at DiaSys Diagnostic Systems GmbH.
5. Thomas L. Labor und Diagnose. 7th ed. Frankfurt: TH-Books Verlagsgesellschaft; 2008. p. 197.
6. Fogh-Andersen, N.; D'Orazio, P.; Proposal for standardizing direct-reading biosensors for blood glucose; Clin Chem 44:3;(1998) 655–659.
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. Thomas L ed. Clinical Laboratory Diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft, 1998. p. 475 - 479.
9. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: mechanisms, detection and prevention. ClinChemLabMed 2007;45(9):1240-1243.

Glucose IS

Summary [1,2]

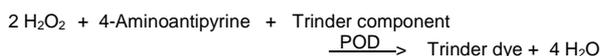
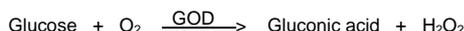
Measurement of glucose concentration in serum, plasma or whole blood is mainly used in diagnosis and monitoring of treatment in diabetes mellitus. Other applications are the exclusion of pancreatic islet cell carcinoma as well as the evaluation of carbohydrate metabolism in various diseases.

Method

“GOD-PAP“: Enzymatic photometric test

Principle

Determination of glucose after enzymatic oxidation by glucose oxidase. The colorimetric indicator is a Trinder dye which is generated from 4-aminoantipyrine and a Trinder component by hydrogen peroxide under the catalytic action of peroxidase (Trinder's reaction).



Warnings and Precautions

1. The reagent contains sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.
2. In very rare cases, samples of patients with gammopathy might give falsified results [9].
3. N-acetylcysteine (NAC), acetaminophen and metamizole medication leads to falsely low results in patient samples.
4. Please refer to the safety data sheets 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.
5. For professional use only!

Specimen

Capillary blood (taken with heparinized capillary) or venous whole blood (with NaF)

Discard contaminated specimens!

Specimen stability [1,3,4]

The determination of glucose has to be performed directly after sampling in order to avoid falsely low glucose values due to in vitro glycolysis. If immediate glucose determination is not possible, glycolysis inhibitors have to be added to the samples (venous whole blood), e.g. fluoride, which stabilize the glucose concentration for 72 h at room temperature. After capillary sampling, glucose determination must be performed immediately.

Sample preparation:

For sample preparation, sample cups InnovaStar® 10/500 (magenta cups) and open-end capillaries (10 µL/ heparinized) are required. Take the patient sample with an open-end capillary as described in the user manual. Put the filled capillary into the sample cup. Mix the sample and start the measurement directly.

Assay Procedure

Application is read by the ParamCard (see user manual InnovaStar®).

Hematocrit-corrected glucose concentration [6]

InnovaStar® is able to calculate a glucose plasma value from a whole blood sample, if plasma correction is activated while *reading the ParamCard for the first time*. If plasma correction is active, results will be marked "GLP" (use reference range for serum/plasma).

The correction is carried out by a simultaneously determined individual hematocrit value which results from division of hemoglobin concentration by a factor. If the hemoglobin value is <5 g/dL or >25 g/dL, no correction is effected and the results is flagged as "GL*".

If the method "GLP" is not selected, uncorrected whole blood values "GLU" are reported (use reference range for whole blood).

Analyte, unit and plasma correction can be chosen *when reading the ParamCard for the first time*.

Calibration and Calculation

The result is calculated by factor, no calibration has to be done. The factor is stored on the ParamCard included in the reagent kit and is read after receipt of the reagent (see user manual InnovaStar®).

Conversion factor

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

Controls

For internal quality control, DiaSys GL Control N and P controls should be assayed. Each user should establish corrective action in case of deviation in control recovery.

	Cat. No.	Kit size
GL Control N	920 536	50 x 650 µL
GL Control P	920 537	50 x 650 µL

Performance Characteristics

Measuring range

The test has been developed to determine glucose concentrations within a measuring range from 15 - 800 mg/dL (0.83 - 44.4 mmol/L).

Specificity/Interferences

No interference was observed by ascorbic acid up to 30 mg/dL, bilirubin up to 60 mg/dL and lipemia up to 2000 mg/dL triglycerides. Glucose values which are determined in whole blood depend on hematocrit, proteins, lipoproteins and other corpuscle contents compared to glucose values which are measured in plasma. When using capillary or venous whole blood, decreased glucose values are obtained in newborns due to high hematocrit values compared to values obtained using capillary plasma. Therefore, neither capillary nor venous whole blood should be used for glucose determination during the neonatal period, if no hematocrit correction is effected. Hematocrit correction on DiaSys InnovaStar® is possible for hemoglobin concentrations from 5 to 25 g/dL. [1,5]. For further information on interfering substances refer to Young DS [7].

Sensitivity/Limit of Detection

The lower limit of detection is 2.0 mg/dL (0.11 mmol/L).

Precision

Intra-assay precision n = 20	Mean [mg/dL]	SD [mg/dL]	CV [%]
Sample 1	94.9	2.17	2.29
Sample 2	125	1.59	1.27
Sample 3	286	5.16	1.81

Inter-assay precision n = 20	Mean [mg/dL]	SD [mg/dL]	CV [%]
Sample 1	81.2	2.71	3.34
Sample 2	271	2.86	1.06
Sample 3	114	3.76	3.29

Method Comparison

A comparison of DiaSys Glucose IS (y) with a commercially available test (x) using 56 samples gave the following results: $y = 0.969x - 0.957$ mg/dL; $r = 0.996$

Reference Range [1]

Children* (fasting)	[mg/dL]	[mmol/L]
	Serum/Plasma	
1 – 6 year(s)	74 – 127	4.1 – 7.0
7 – 19 years	70 – 106	3.9 – 5.9

* Intervals for serum and plasma; the 2.5th and 97.5th percentile are listed. For capillary whole blood approximately the same intervals can be assumed. The values in venous whole blood are approx. 10% lower.

Adults (fasting)	Whole blood	
Capillary whole blood	70 - 100	3.9 – 5.5
Venous whole blood	60 - 100	3.3 – 5.5

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

Hemoglobin IS

Summary [8]

The hemoglobin concentration combined with hematocrit and RBC count is an important criterion for diagnosis and differentiation of anemias, erythrocytoses and polycythemias.

Principle

Photometric determination of hemoglobin concentration at 540 nm

Warnings and Precautions

- The reagent contains sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.
- Data evaluation for Hemoglobin IS was made with samples from adult donors only.
- Samples showing clinical disorders such as thalassemias or hemoglobinopathies must not be determined with the reagent Glucose/Hemoglobin IS.
- In very rare cases, samples of patients with gammopathy might give falsified results. [9]
- Please refer to the safety data sheets 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.
- For professional use only!

Specimen

Capillary blood (taken with heparinized capillary) or venous whole blood (with NaF)

Discard contaminated specimens!

Specimen stability

The determination of hemoglobin has to be performed directly after sampling. Blood collection tubes have to be thoroughly mixed by inversion 10 times before testing. Do not shake!

Sample preparation

For sample preparation sample cups InnovaStar® 10/500 (magenta cups) and open-end capillaries (10 µL/ heparinized) are required. Take the patient sample with an open-end capillary as described in the user manual. Put the filled capillary into the sample cup. Mix the sample and start the measurement directly.

Assay procedure

Application is read by the ParamCard (see user manual InnovaStar®).

Analyte and unit ([g/dL] or [mmol/L]) can be chosen *when reading the ParamCard for the first time*.

Calibration and Calculation

The result is calculated by factor. No calibration has to be done. The factor is stored on the ParamCard included in the reagent kit and is read after receipt of the reagent (see user manual InnovaStar®).

Conversion factor [8]

Hemoglobin [g/dL] x 0.621 = Hemoglobin [mmol/L]

Hemoglobin [mmol/L] x 1.61 = Hemoglobin [g/dL]

Controls

For internal quality control, DiaSys GL Control N and P should be assayed. Each laboratory should establish corrective action in case of deviation in control recovery.

	Cat. No.	Kit size
GL Control N	920 536	50 x 650 µL
GL Control P	920 537	50 x 650 µL

Performance Characteristics

Measuring range

The test has been developed to determine hemoglobin concentrations from 5 up to 25 g/dL.

Specificity/Interferences

No interference was observed by bilirubin up to 60 mg/dL and lipemia up to 2000 mg/dL triglycerides.

Sensitivity/Limit of Detection

The lower limit of detection is 2.5 g/dL.

Precision

Total n = 20	Mean [g/dL]	SD [g/dL]	CV [%]
Sample 1	9.62	0.082	0.85
Sample 2	14.5	0.115	0.79
Sample 3	19.3	0.165	0.86

Intra-assay precision n = 20	Mean [g/dL]	SD [g/dL]	CV [%]
Sample 1	9.12	0.063	0.70
Sample 2	15.0	0.151	1.01
Sample 3	19.8	0.131	0.66

Method Comparison

A comparison of DiaSys Hemoglobin IS (y) with DiaSys Hemoglobin FS (x) using 83 samples gave the following results:

$Y = 1.0 x + 0.2 \text{ g/dL}; r = 0.990$

Reference Range [8]

	[g/dL]	[mmol/L]
Adults:		
Female	12.3 – 15.3	7.62 – 9.48
Male	14.0 – 17.5	8.67 – 10.8
Children:		
2 – 2.5 months	9.2 – 15.0	5.71 – 9.32
3 – 3.5 months	9.6 – 12.8	5.96 – 7.95
5 – 7 months	10.1 – 12.9	6.27 – 8.01
8 – 10 months	10.5 – 12.9	6.52 – 8.01
11 - 13.5 months	10.7 – 13.1	6.65 – 8.14
1.5 – 3 years	10.8 – 12.8	6.71 – 7.95
5 years	11.1 – 14.3	6.89 – 8.88
10 years	11.9 – 14.7	7.39 – 9.13
12 years	11.8 – 15.0	7.33 – 9.32
15 years	12.8 – 16.8	7.95 – 10.4

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

Manufacturer



DiaSys Diagnostic Systems GmbH
Alte Strasse 9 65558 Holzheim Germany