



INSTRUCTIONS FOR USE

VITROS GLU Slides

GLU

Glucose

Intended Use

For in vitro diagnostic use only.

VITROS GLU Slides quantitatively measure glucose (GLU) concentration in serum, plasma, urine, and cerebrospinal fluid (CSF).

Summary and Explanation of the Test

Glucose is a primary cellular energy source. Fasting plasma glucose concentrations and tolerance to a dose of glucose are used to establish the diagnosis of diabetes mellitus and disorders of carbohydrate metabolism. Glucose measurements are used to monitor therapy in diabetics and in patients with dehydration, coma, hypoglycemia, insulinoma, acidosis, and ketoacidosis.¹

Principles of the Procedure

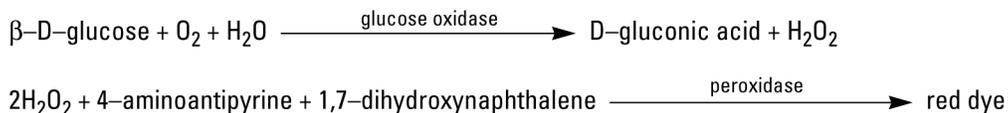
The VITROS GLU Slide is a dry, multilayered, analytical element coated on a polyester support.

A 10 μ L drop of patient sample is deposited on the slide where the spreading layer promotes the uniform distribution of the sample and permits an even penetration of solute molecules into the underlying reagent layer. The oxidation of sample glucose is catalyzed by glucose oxidase to form hydrogen peroxide and gluconate. This reaction is followed by an oxidative coupling catalyzed by peroxidase in the presence of dye precursors to produce a dye. The intensity of the dye is measured by reflected light.

The dye system used is closely related to that first reported by Trinder.² The chemistry of the glucose slides has been described by Curme et al.³

Test Type	Wavelength	Assay Time and Temperature
Colorimetric	540 nm	Approximately 5 minutes at 37°C

Reaction Sequence

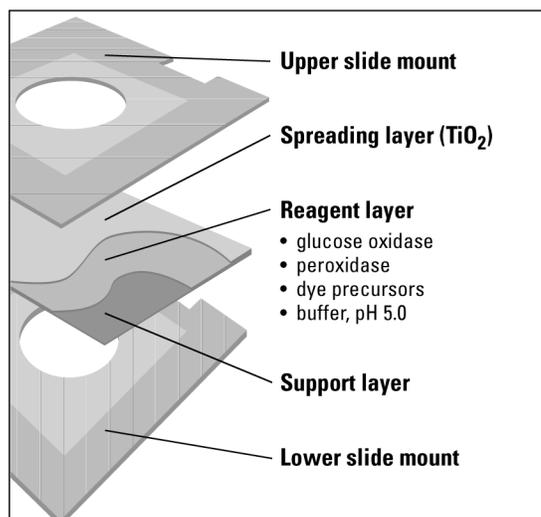


Reagents

Slide Ingredients

Reactive ingredients are glucose oxidase (*Aspergillus Niger*, E.C.1.1.3.4); peroxidase (horseradish root, E.C.1.11.1.7); 1,7-dihydroxynaphthalene (dye precursor); and 4-aminoantipyrine hydrochloride (dye precursor). Other ingredients include pigment, binders, buffer, surfactants, stabilizers, and cross-linking agent.

Slide Diagram



Slide Labeling

The cartridge's outer carton is labeled with the test name, slide lot number, expiration date, and required storage temperature.

Slide Cartridge Handling

CAUTION: Protect the inner wrapper from damage before opening.

- Do not drop a case of cartridges.
- Do not cut into the inner wrapper with a sharp instrument when opening the case.

Slide Storage

Unopened slide cartridges:

- Store at or below 2°–8°C (36°–46°F).
- Do not store with or near hydrogen peroxide.

Cartridges in the system's slide supply:

- Leave in the slide supply for no more than two weeks, then replace with a fresh cartridge.
- Leave in the slide supply when the system is turned off for up to two hours.
- Verify performance with control materials:
 - If the system is turned off for more than two hours
 - After reloading cartridges that have been removed from the slide supply and stored for later use

Slide Stability

VITROS GLU Slides are stable until the expiration date on the carton when they are stored and handled as specified.

Slide Preparation

- Remove slide cartridges from storage.
- The slide cartridge must reach room temperature, 18°–28°C (64°–82°F), before it is unwrapped and loaded into the slide supply. Allow the cartridge to warm up at least:
 - 60 minutes after removing from the freezer
 - or
 - 30 minutes after removing from the refrigerator
- Remove the inner wrapper and immediately load into the slide supply.

NOTE: Load the cartridges within 24 hours after they reach room temperature.

Specimen Collection and Preparation

Serum and Plasma Specimens

Patient Preparation

No special patient preparation is necessary.

Recommended Specimen Types

Serum; heparin, sodium fluoride/potassium oxalate, and EDTA plasma.

Special Precautions

Particulate matter (for example, fibrin) in sufficient quantity may coat the spreading layer and limit diffusion of oxygen, causing a negative interference. To minimize particulate matter, do not centrifuge specimens until clotting is complete.

Specimen Collection and Preparation

- Collect specimens using standard laboratory procedures.^{4,5}
- Refer to the operator's manual section on sample handling for recommended minimum specimen volumes for your system.
- Serum:
 - Centrifuge specimen at 1000X g for 10 minutes and remove serum from the clot within 30 minutes after collecting the specimen to avoid metabolism of glucose by the cells (approximately 7% per hour at room temperature).⁶
- Heparin or EDTA plasma:
 - Follow manufacturer's recommendations for mixing anticoagulant with specimens.
 - Centrifuge specimen at 1000X g for 10 minutes and remove plasma from the cells within 30 minutes after collecting the specimen to avoid metabolism of glucose by the cells (approximately 7% per hour at room temperature).⁷
- Sodium fluoride/potassium oxalate plasma:
 - Follow manufacturer's recommendations for mixing anticoagulant with specimens.
 - Centrifuge specimens and remove the plasma from the cells within 24 hours of collection.⁸

Handling and Storage Conditions

- Handle specimens as biohazardous material.
- Handle specimens in stoppered containers to avoid contamination and evaporation.
- Storage requirements:⁹
 - Store at room temperature up to 24 hours
 - Refrigerate up to 7 days
 - Freeze at or below -18°C (0°F) for storage up to 1 year

Urine Specimens***Patient Preparation***

No special patient preparation is necessary.

Recommended Specimen Types

Urine. Urine preservatives are not necessary and may interfere.

Specimen Collection and Preparation

- Collect specimens using standard laboratory procedures.¹⁰
- Refrigerate during collection and keep refrigerated until analysis.¹¹
- Refer to the operator's manual section on sample handling for recommended minimum specimen volumes for your system.

Handling and Storage Conditions

- Handle specimens as biohazardous material.
- Handle specimens in stoppered containers to avoid contamination and evaporation.
- Storage requirements:
 - Refrigerate at 2°–8°C (36°–46°F) specimens that cannot be analyzed immediately.

CSF Specimens***Patient Preparation***

No special patient preparation is necessary.

Recommended Specimen Types

Cerebrospinal fluid (CSF).

Specimen Collection and Preparation

- Collect specimens using standard laboratory procedures.¹²
- Centrifuge specimen and remove the supernatant within 1 hour of collection.¹³

Handling and Storage Conditions

- Storage requirements:
 - Refrigerate at 2°–8°C (36°–46°F) for up to 7 days¹⁴.

Testing Procedure**Materials Required But Not Provided**

The following items are required to perform the test for GLU:

- VITROS Chemistry Calibrator Kit 1
- Quality-control materials, such as VITROS Performance Verifiers
- For dilution, VITROS 7% BSA

Operating Instructions

Refer to the operator's manual for complete instructions on operation of your system.

Sample Dilution

If samples show glucose concentrations that exceed the system's reportable (dynamic) range, follow this procedure.

1. Dilute the samples with the diluent indicated below.

Serum or plasma: VITROS 7% BSA

Urine: Reagent-grade water or isotonic saline.

2. Reanalyze.
3. Multiply the results by the dilution factor to obtain the original sample's glucose concentration.

Calibration

Required Calibrators

- VITROS Chemistry Calibrator Kit 1
- The same calibrators are used for serum, urine, and CSF glucose; however, distinctive supplementary assigned values (SAVs) are applied for each body fluid.

Calibrator Preparation, Handling, and Storage

Refer to the calibrator package insert for information about reconstitution and use of the Chemistry Calibrator Kit.

Calibration Procedure

Refer to the calibration section of your operator's manual.

When to Calibrate

- Calibrate when the slide lot number changes.
- Calibrate when critical system parts are replaced due to service or maintenance.
- If quality-control results are consistently outside acceptable limits, calibration might be required. Refer to your operator's manual for more detail.
- Calibrate when government regulations require. In the US, CLIA regulations require calibration or calibration verification at least once every six months.

Reference Method

Calibration is traceable to the hexokinase reference method.¹⁵

Calibration Model

End-point colorimetry (described in your operator's manual).

Quality Control

Procedure Recommendations

- Handle quality-control materials as biohazardous material.
- Analyze quality-control materials in the same manner as patient samples, before or during patient sample processing.
- Analyze control materials at least once per day to verify system performance.
- Choose control levels that check the clinically relevant range.
- Refer to the quality control section in your operator's manual for additional information on quality-control procedures for VITROS Systems.
- Refer to *Internal Quality Control Testing: Principles and Definitions* for general quality-control recommendations.¹⁶

Quality-Control Material Selection

- VITROS Performance Verifiers are specially formulated for use with VITROS Systems.
- VITROS Liquid Performance Verifier is available for use as a CSF control material.
- Other control materials may show a difference when compared with other glucose methods if they:
 - Depart from a true human serum/plasma matrix
 - Contain high concentrations of preservatives, stabilizers, or other nonphysiological additives
- Do not use control materials stabilized with ethylene glycol.

Quality-Control Material Preparation and Storage

Refer to the manufacturer's product literature for preparation, storage, and stability information.

Expected Values and Reporting Results

Reference Interval

	Conv. Units (mg/dL)	SI Units (mmol/L)	Alternate Units (g/L)
Serum			
Male	75–110	4.2–6.1	0.8–1.1
Female	65–105	3.6–5.8	0.7–1.1
Urine¹⁷			
24-hour	< 500 mg/day*	< 2.8 mmol/day**	< 0.5 g/day***
Random samples	< 30	< 1.7	< 0.3
CSF¹⁸			
	40–70	2.2–3.9	0.4–0.7

* Glucose concentration (mg/dL) x 24-hour volume (dL) = mg/day.

** Glucose concentration (mmol/L) x 24-hour volume (L) = mg/day.

*** Glucose concentration (g/L) x 24-hour volume (L) = g/day.

These reference intervals are the central 95% of results from an internal study of 440 fasting, apparently healthy adults from a working population. Each laboratory should verify the validity of these intervals for the population it serves.

Reporting Units and Unit Conversion

Conventional Units	SI Units	Alternate Units
mg/dL	mmol/L (mg/dL x 0.05551)	g/L (mg/dL x 0.01)

Limitations of the Procedure**Serum**

- Hemolysis causes a decrease in glucose results of up to 10% in the presence of 3+ hemolysis, equivalent to 250 mg/dL (0.16 mmol/L) of hemoglobin.
This interference is caused by catalase or other cellular constituents released during lysis. However, the extent of bias is highly correlated with the degree of hemolysis seen in the sample.
- Elevated lipids may limit diffusion of oxygen to the reactants. Dilute grossly lipemic samples twofold before analysis.

CSF

None have been identified.

Urine

Urine preservatives that did not interfere with the test for urine glucose (< 2% change):

- 10% thymol in isopropanol (6.7 mL/L)
- Toluene (1.3 mL/L)
- Boric acid (5.2 g/L)
- Borocon powder (15 mg/mL)

Table of Known Interfering Substances

The VITROS GLU method was screened for interfering substances. The following substances, when tested at the concentrations indicated, caused the bias shown.

Interferent*	Conventional Units			SI Units		
	Interferent Concentration	Analyte Conc. (mg/dL)	Average Bias	Interferent Concentration	Analyte Concentration	Average Bias
SERUM/PLASMA						
Total protein	5 g/dL	100	-5 mg/dL	50 g/L	5.55 mmol/L	-0.28 mmol/L
	10 g/dL	100	+6 mg/dL	100 g/L	5.55 mmol/L	+0.33 mmol/L
URINE						
Ascorbic acid	6 mg/dL	30	-6 mg/dL	340 µmol/L	1.66 mmol/L	-0.33 mmol/L
Glacial acetic acid	10 mL/L urine	30	-10%	10 mL/L urine	1.66 mmol/L	-10%
Hydrochloric acid (conc.)	6.7 mL/L urine	30	+13%	6.7 mL/L urine	1.66 mmol/L	+13%
Borocon tablets	1 tablet/15 mL urine	30	+13%	1 tablet/15 mL urine	1.66 mmol/L	+13%
Sodium fluoride	10 mg/mL urine	30	+9%	10 mg/mL urine	1.66 mmol/L	+9%

* It is possible that other interfering substances may be encountered. These results are representative; however, your results may differ somewhat due to test-to-test variation. The degree of interference at concentrations other than those listed might not be predictable.

Other Limitations

Some drugs and patient conditions are known to alter glucose concentrations in vivo. A compilation of this information is available in the literature.^{19, 20}

Performance Characteristics

Reportable Range (Dynamic Range)

	Conventional Units (mg/dL)	SI Units (mmol/L)	Alternate Units (g/L)
Serum	20.0–625.0	1.11–34.69	0.20–6.25
Urine	20.0–650.0	1.11–36.08	0.20–6.50
CSF	20.0–650.0	1.11–36.08	0.20–6.50

Refer to Sample Dilution under “Testing Procedure” for out-of-range samples.

Sensitivity

The lower limit of the reportable (dynamic) range is 20.0 mg/dL (1.11 mmol/L).

Precision

Precision was evaluated with quality-control materials on VITROS 250, 700, and 950 Chemistry Systems.

These results are guidelines. Variables such as instrument maintenance, environment, slide handling/storage, control material reconstitution, and sample handling can affect the reproducibility of test results.

GLU Precision (Serum)

SYSTEM	Conventional Units (mg/dL)			SI Units (mmol/L)			Within Lab CV%**	No. Observ.	No. Days
	Mean Conc.	Within Day SD*	Within Lab SD**	Mean Conc.	Within Day SD*	Within Lab SD**			
VITROS 250	86	0.5	1.5	4.8	0.03	0.08	1.7	77	20
	286	1.4	4.1	15.9	0.08	0.23	1.4	78	20
VITROS 700	89	1.0	1.1	4.9	0.05	0.06	1.2	185	20
	92	1.0	1.2	5.1	0.06	0.07	1.3	187	20
	239	2.8	3.6	13.3	0.15	0.20	1.5	186	20
	308	3.0	3.6	17.1	0.16	0.20	1.2	185	20
	488	5.2	7.1	27.1	0.29	0.39	1.5	184	20
VITROS 950	83	0.5	1.1	4.6	0.03	0.06	1.4	91	23
	270	1.5	2.6	15.0	0.08	0.14	1.0	92	23

GLU Precision (Urine)

SYSTEM	Conventional Units (mg/dL)			SI Units (mmol/L)			Within Lab CV%**	No. Observ.	No. Days
	Mean Conc.	Within Day SD*	Within Lab SD**	Mean Conc.	Within Day SD*	Within Lab SD**			
VITROS 250	44	0.3	0.4	2.5	0.02	0.02	0.9	88	22
	77	1.1	1.5	4.3	0.06	0.08	1.9	84	21
	232	2.9	4.7	12.9	0.16	0.26	2.0	88	22
	278	2.0	3.8	15.4	0.11	0.21	1.4	88	22
VITROS 700	29	0.3	0.7	1.6	0.02	0.04	2.5	108	18
	148	1.1	1.7	8.2	0.06	0.09	1.2	108	18
	192	1.7	2.6	10.7	0.09	0.15	1.4	108	18
	230	1.9	2.9	12.8	0.10	0.16	1.3	108	18
	303	2.1	3.8	16.8	0.12	0.21	1.3	108	18
VITROS 950	50	0.3	0.3	2.8	0.02	0.02	0.7	93	23
	307	2.0	3.0	17.0	0.11	0.17	1.0	92	23

GLU Precision (CSF)

SYSTEM	Conventional Units (mg/dL)			SI Units (mmol/L)			Within Lab CV%**	No. Observ.	No. Days
	Mean Conc.	Within Day SD*	Within Lab SD**	Mean Conc.	Within Day SD*	Within Lab SD**			
VITROS 250	41	0.4	0.8	2.3	0.02	0.05	2.1	80	20
	85	0.7	0.8	4.7	0.04	0.04	0.9	80	20
VITROS 700	35	0.6	1.3	1.9	0.03	0.07	3.7	108	18
	59	0.6	1.1	3.2	0.03	0.06	1.9	108	18
	63	0.9	1.0	3.5	0.05	0.05	1.6	108	18
	122	1.3	2.0	6.8	0.07	0.11	1.6	108	18
VITROS 950	48	0.3	0.4	2.7	0.02	0.02	0.9	92	23
	92	0.5	1.0	5.1	0.03	0.05	1.1	92	23

* Within Day precision was determined using two runs/day with two to three replications.

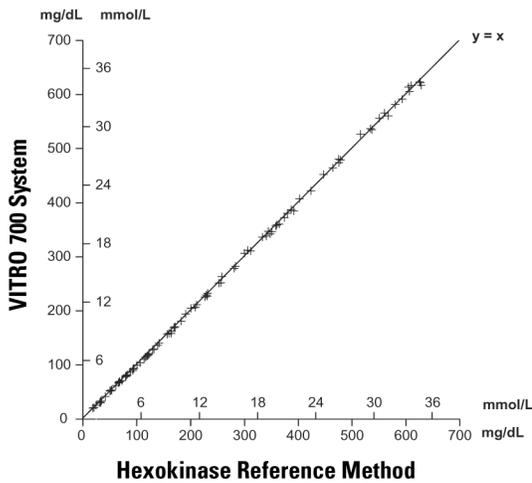
** Within Lab precision was determined using a single lot of slides and calibrating weekly.

Accuracy

The plots and tables show the results of a comparison of serum, urine, and CSF specimens analyzed on the VITROS 700 System with those analyzed using the hexokinase reference method.

The tables also show the results of comparisons between the VITROS 700 System and a commercially available method, and comparisons of the VITROS 250 and 950 Systems with the VITROS 700 System.

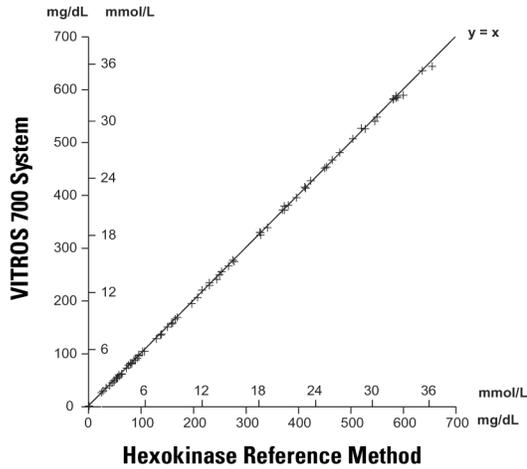
GLU/Serum



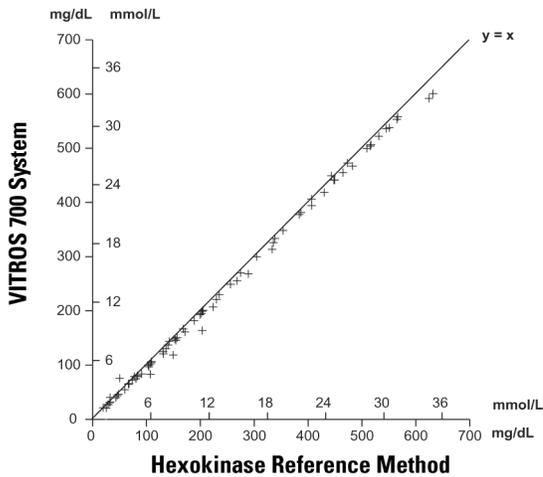
GLU

Glucose

GLU/CSF



GLU/Urine



Method Comparison (Serum)

	n	Slope	Correlation Coefficient	Conventional Units (mg/dL)			SI Units (mmol/L)		
				Range of Sample Concentration	Intercept	Sy.x	Range of Sample Concentration	Intercept	Sy.x
700 System vs. reference method	96	1.00	1.000	20–623	-0.67	3.39	1.1–34.6	-0.04	0.19
250 System vs. 700 System	55	1.00	1.000	63–621	0.03	3.48	3.5–34.5	0.00	0.19
950 System vs. 700 System	126	0.99	0.999	28–616	0.02	1.72	1.6–34.2	0.00	0.09

Method Comparison (Urine)

	n	Slope	Correlation Coefficient	Conventional Units (mg/dL)			SI Units (mmol/L)		
				Range of Sample Concentration	Intercept	Sy.x	Range of Sample Concentration	Intercept	Sy.x
700 System vs. reference method	77	0.98	0.998	21–601	-2.20	8.28	1.1–33.4	-0.12	0.46
250 System vs. 700 System	53	1.02	1.000	6–688	-1.11	4.60	0.3–38.2	-0.06	0.26
700 System vs. Boehringer Mannheim Glucose/HK (Hitachi 747)	216	0.90	0.992	26–617	-6.21	21.38	1.4–34.3	-0.34	1.19
950 System vs. 700 System	100	1.00	0.999	25–561	0.23	1.42	1.4–31.1	0.01	0.08

Method Comparison (CSF)

	n	Slope	Correlation Coefficient	Conventional Units (mg/dL)			SI Units (mmol/L)		
				Range of Sample Concentration	Intercept	Sy.x	Range of Sample Concentration	Intercept	Sy.x
700 System vs. reference method	76	1.00	1.000	1–644	0.62	2.86	0.1–35.7	0.03	0.16
250 System vs. 700 System	43	1.01	1.000	8–663	-0.97	4.78	0.5–36.8	-0.05	0.27
700 System vs. Boehringer Mannheim Glucose/HK (Hitachi 747)	282	0.96	1.000	29–549	1.77	4.87	1.6–30.5	0.10	0.27
950 System vs. 700 System	102	1.00	0.999	21–593	0.06	1.48	1.2–32.9	0.00	0.08

Specificity

The following substances were tested with VITROS GLU Slides and found not to interfere (bias < 4.4 mg/dL):

Compound	Concentration	Compound	Concentration
Acetaminophen	5 mg/dL	Gentisic acid	0.5 mg/dL
Acetylsalicylic acid	30 mg/dL	Hypaque	500 mg/dL
<i>p</i> -Aminosalicylic acid	23 mg/dL	Iodide	2 mEq/L
Ascorbic acid	3 mg/dL	Isoniazid	0.4 mg/dL
Bilirubin	20 mg/dL	L-dopa	0.6 mg/dL
Chlorothiazide	3 mg/dL	6-Mercaptopurine	1.5 mg/dL
Creatinine	15 mg/dL	Sulfathiazole	6 mg/dL
Dextran	1000 mg/dL	Tyrosine	24 mg/dL
Ethanol	300 mg/dL	Urea nitrogen	100 mg/dL
Fructose	30 mg/dL	Xylose	25 mg/dL
Galactose	60 mg/dL		

References

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GLU

Glucose

Revision History

Date of Revision:	Version:	Description:
2002APR19	1.0	New format, technically equivalent to 11/96.

When this Instructions For Use is replaced, sign and date below and retain as specified by local regulations or laboratory policies, as appropriate.

Signature

Obsolete Date

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100 Indigo Creek Drive
Rochester, NY 14626-5101



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