VITROS Products Chemistry

# INSTRUCTIONS FOR USE

# GLU

## VITROS Chemistry Products GLU Slides

**Glucose**

**REF** 170 7801

## Intended Use

For *in vitro* diagnostic use only.

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

## 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

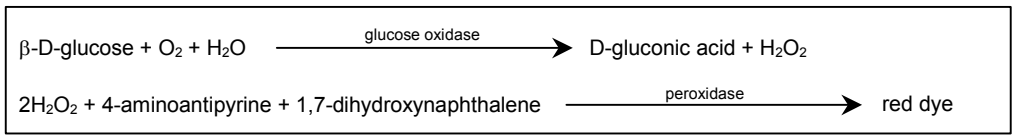
The VITROS GLU Slide method is performed using the VITROS GLU Slides and the VITROS Chemistry Products Calibrator Kit 1 on VITROS Chemistry Systems.

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

A drop of patient sample is deposited on the slide and is evenly distributed by the spreading layer to the underlying layers. 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]

### Reaction Sequence




## Test Type and Conditions

**Test Type and Conditions for GLU**

| Test Type | VITROS System | Approximate Incubation Time | Temperature | Wavelength | Sample Drop Volume |
|---|---|---|---|---|---|
| Colorimetric | 5,1 FS, 950, 750, 550, 250 | 5 minutes | 37°C (98.6°F) | 540 nm | 10 µL |

## Warnings and Precautions

For *in vitro* diagnostic use only.

Take care when handling materials and samples of human origin. Since no test method can offer complete assurance that infectious agents are absent, consider all clinical specimens, controls, and calibrators potentially infectious. Handle specimens, solid and liquid waste, and test components in accordance with local regulations and NCCLS Guideline M29[4] or other published biohazard safety guidelines.

For specific warnings and precautions for calibrators, quality control materials, and other components, refer to the Instructions for Use for the appropriate VITROS product, or to other manufacturer's product literature.

# Reagents

## Slide Ingredients

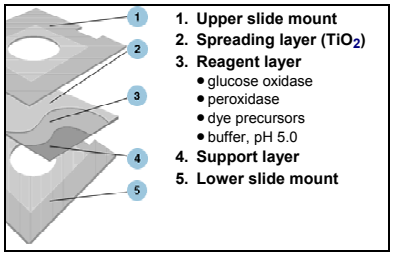
### *Reactive ingredients per cm²*

Glucose oxidase (*Aspergillus Niger*, E.C.1.1.3.4) 0.77 U; peroxidase (horseradish root, E.C.1.11.1.7) 3.6 U; 1,7-dihydroxynaphthalene (dye precursor) 67 µg and 4-aminoantipyrine hydrochloride (dye precursor) 0.11 mg.

### *Other ingredients*

Pigment, binders, buffer, surfactants, stabilizers and cross-linking agent.

**Slide Diagram**




## Cartridge Handling

**CAUTION:** **Do not use slide cartridges with damaged or incompletely sealed packaging.**

- Inspect the packaging for signs of damage.
- Be careful when opening the outer packaging with a sharp instrument so as to avoid damage to the individual product packaging.

## Cartridge Preparation

**IMPORTANT:** *The slide cartridge must reach room temperature, 18°–28°C (64°–82°F), before it is unwrapped and loaded into the slide supply.*

1. Remove the slide cartridges from storage.
2. Warm the wrapped cartridge at room temperature for 30 minutes when taken from the refrigerator or 60 minutes from the freezer.
3. Unwrap and load the cartridge into the slide supply.

**NOTE:** Load the cartridges within 24 hours after they reach room temperature, 18°–28°C (64°–82°F).

## Slide Storage and Stability

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

**Slide Storage and Stability for GLU**

| Slide Cartridges | Specimen Type Used | Storage Condition | | Stability |
|---|---|---|---|---|
| Unopened* | All recommended specimens | Frozen | ≤-18°C (≤0°F) | Until expiration date |
| | Plasma (Sodium fluoride/ potassium oxalate) | Refrigerated | 2°–8°C (36°–46°F) | ≤4 months |
| | Serum, Plasma (EDTA, Heparin), Urine, CSF | Refrigerated | 2°–8°C (36°–46°F) | Until expiration date |
| Opened | All recommended specimens | On-analyzer | System turned on | ≤1 week |
| | | On-analyzer | System turned off | ≤2 hours |

* Do not store with or near hydrogen peroxide.

- Verify performance with quality control materials:
  - If the system is turned off for more than 2 hours.
  - After reloading cartridges that have been removed from the slide supply and stored for later use.

# Specimen Requirements

**WARNING:** ***Handle specimens as biohazardous material.***

## Specimens Recommended

- Serum
- Plasma: EDTA
  Heparin
  Sodium fluoride/potassium oxalate (see the Slide Storage and Stability table for slide storage when using this specimen type)
- Urine
- CSF

**IMPORTANT:** *Certain collection devices have been reported to affect other analytes and tests.* [5] *Confirm that your collection devices are compatible with this test.*

## Specimens Not Recommended

- Urine: Preservatives

## Serum and Plasma

### *Specimen Collection and Preparation*

Collect specimens using standard laboratory procedures. [6, 7]

**NOTE:** For details on minimum fill volume requirements, refer to the operating instructions for your VITROS Chemistry System.

**Patient Preparation**

- No special patient preparation is necessary.

**Special Precautions**

- For the effect of sample hemolysis on test results, refer to "Limitations of the Procedure."
- Grossly lipemic samples must be diluted twofold prior to analysis. Refer to "Sample Dilution" for dilution instructions.
- For the effect of elevated lipids on test results, refer to "Limitations of the Procedure."
- 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.
- 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). [6]
- 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]

**IMPORTANT:** *See the Slide Storage and Stability table for slide storage when using sodium fluoride/potassium oxalate plasma.*

### *Specimen Handling and Storage*

**WARNING:** ***Handle specimens as biohazardous material.***

- Handle and store specimens in stoppered containers to avoid contamination and evaporation.
- Mix samples by gentle inversion and bring to room temperature, 18°–28°C (64°–82°F), prior to analysis.

**Specimen Storage and Stability for GLU: Serum and Plasma** [8]

| Storage | Temperature | Stability |
|---|---|---|
| Room temperature | 18°–28°C (64°–82°F) | ≤24 hours |
| Refrigerated | 2°–8°C (36°–46°F) | ≤7 days |
| Frozen | ≤-18°C (≤0°F) | ≤1 year |

### Urine

#### *Specimen Collection and Preparation*

Collect specimens using standard laboratory procedures. [9]

**NOTE:** For details on minimum fill volume requirements, refer to the operating instructions for your VITROS Chemistry System.

- Keep refrigerated until analysis. [10]

**Patient Preparation**

- No special patient preparation is necessary.

#### *Specimen Handling and Storage*

- Handle and store specimens in stoppered containers to avoid contamination and evaporation.
- Mix samples by gentle inversion and bring to room temperature, 18°–28°C (64°–82°F), prior to analysis.

**Specimen Storage and Stability for GLU: Urine** [9]

| Storage | Temperature | Stability |
|---|---|---|
| Refrigerated | 2°–8°C (36°–46°F) | Not determined |

### CSF

#### *Specimen Collection and Preparation*

- Collect specimens using standard laboratory procedures. [11]

**NOTE:** For details on minimum fill volume requirements, refer to the operating instructions for your VITROS Chemistry System.

**Patient Preparation**

- No special patient preparation is necessary.

**Special Precautions**

- Centrifuge specimen and remove the supernatant within 1 hour of collection. [8]

#### *Specimen Handling and Storage*

- Handle and store specimens in stoppered containers to avoid contamination and evaporation.
- Mix samples by gentle inversion and bring to room temperature, 18°–28°C (64°–82°F), prior to analysis.

**Specimen Storage and Stability for GLU: CSF** [8]

| Storage | Temperature | Stability |
|---|---|---|
| Refrigerated | 2°–8°C (36°–46°F) | ≤7 days |

## Testing Procedure

### Materials Provided

- VITROS Chemistry Products GLU Slides

### Materials Required But Not Provided

- VITROS Chemistry Products Calibrator Kit 1
- Quality control materials, such as VITROS Chemistry Products Performance Verifier I and II for serum and plasma tests or VITROS Chemistry Products Liquid Performance Verifier I and II for CSF tests.
- VITROS Chemistry Products 7% BSA
- Isotonic saline or reagent-grade water
- VITROS Chemistry Products FS Diluent Pack 2 (BSA/Saline) (for on-analyzer dilution)
- VITROS Chemistry Products FS Diluent Pack 3 (Specialty Diluent/Water) (for on-analyzer dilution)

### Operating Instructions

- Check reagent inventories at least daily to ensure that quantities are sufficient for the planned workload.
- For additional information, refer to the operating instructions for your VITROS Chemistry System.

**IMPORTANT:** *Bring all fluids and samples to room temperature, 18°–28°C (64°–82°F), prior to analysis.*

### Sample Dilution

#### *Serum and Plasma*

If glucose concentrations exceed the system's reportable (dynamic) range or if the sample is grossly lipemic:

**Manual Sample Dilution**

1. Dilute the sample with VITROS 7% BSA.
2. Reanalyze.
3. Multiply the results by the dilution factor to obtain an estimate of the original sample's glucose concentration.

**On-Analyzer Sample Dilution (VITROS 5,1 FS and VITROS 250 only)**

Refer to the VITROS Chemistry System operating instructions for more information on the On-Analyzer Dilution Procedure. For VITROS 5,1 FS, use VITROS Chemistry Products FS Diluent Pack 2 for the dilution.

#### *Urine*

If glucose concentrations exceed the system's reportable (dynamic) range:

**Manual Sample Dilution**

1. Dilute the sample with isotonic saline or reagent-grade water.
2. Reanalyze.
3. Multiply the results by the dilution factor to obtain an estimate of the original sample's glucose concentration.

**On-Analyzer Sample Dilution (VITROS 5,1 FS and VITROS 250 only)**

Refer to the VITROS Chemistry System operating instructions for more information on the On-Analyzer Dilution Procedure. For VITROS 5,1 FS, use VITROS Chemistry Products FS Diluent Pack 2 or VITROS Chemistry Products FS Diluent Pack 3 for the dilution.

## Calibration

### Required Calibrators

- VITROS Chemistry Products Calibrator Kit 1

**NOTE:** The same VITROS Calibrator Kit is used to calibrate serum, urine, and CSF glucose. However, specific supplementary assigned values (SAVs) are applied for each body fluid.

### Calibrator Preparation, Handling, and Storage

Refer to the Instructions for Use for VITROS Calibrator Kit 1.

### Calibration Procedure

Refer to the operating instructions for your VITROS Chemistry System.

### When to Calibrate

Calibrate:

- When the slide lot number changes.
- When critical system parts are replaced due to service or maintenance.
- When government regulations require.
  - For example, in the USA, CLIA regulations require calibration or calibration verification at least once every six months.

The VITROS GLU test may also need to be calibrated:

- If quality control results are consistently outside acceptable range.
- After certain service procedures have been performed.

For additional information, refer to the operating instructions for your VITROS Chemistry System.

### Calculations

Reflectance from the slide is measured at 540 nm after the fixed incubation time. Once a calibration has been performed for each slide lot, glucose concentration in unknown samples can be determined using the software-resident endpoint colorimetric math model and the response obtained from each unknown test slide.

### Validity of a Calibration

Calibration parameters are automatically assessed by the VITROS Chemistry System against a set of quality parameters detailed in the Coefficients and Limits screen (for VITROS 5,1 FS, see the Review Assay Data screen). Failure to meet any of the pre-defined quality parameters results in a failed calibration. The calibration report should be used in conjunction with quality control results to determine the validity of a calibration.

### Reportable (Dynamic) Range

**Reportable (Dynamic) Range for GLU**

| | 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 |

For out-of-range samples, refer to “Sample Dilution.”

### Traceability of the Calibration

Values assigned to the VITROS Chemistry Products Calibrator Kit 1 for glucose are traceable to the Certified NIST (National Institute of Standards and Technology) Reference Material, SRM® (Standard Reference Material) 917b. The Ortho-Clinical Diagnostics calibration laboratory uses SRM® 917b to calibrate the CDC Hexokinase method [12] to support glucose value assignment for VITROS Calibrator Kit 1.

## Quality Control

### Procedure Recommendations

**WARNING:** ***Handle quality control materials as biohazardous material.***

- Choose control levels that check the clinically relevant range.
- Analyze quality control materials in the same manner as patient samples, before or during patient sample processing.
- To verify system performance, analyze control materials:
  - After calibration.
  - According to local regulations or at least once each day that the test is being performed.
  - After specified service procedures are performed. Refer to the operating instructions for your VITROS Chemistry System.
- If control results fall outside your acceptable range, investigate the cause before deciding whether to report patient results.
- For general quality control recommendations, refer *to Statistical Quality Control for Quantitative Measurements: Principles and Definitions; Approved Guideline-Second Edition* [13] or other published guidelines.
- For additional information, refer to the operating instructions for your VITROS Chemistry System.

### Quality Control Material Selection

**IMPORTANT:** *VITROS Performance Verifiers are recommended for use with the VITROS Chemistry System. Evaluate the performance of other commercial control fluids for compatibility with this test before using for quality control.*

- Control materials other than VITROS Performance Verifiers may show a difference when compared with other glucose methods if they:
  - Depart from a true human matrix.
  - Contain high concentrations of preservatives, stabilizers, or other nonphysiological additives.
- Do not use control materials stabilized with ethylene glycol.

#### *Urine*

- For urine specimens, use commercially available urine control materials.

### Quality Control Material Preparation and Storage

Refer to the Instructions for Use for VITROS Chemistry Products Performance Verifier I and II or to other manufacturer's product literature.

## Expected Values and Reporting Units

These reference intervals are based on external studies for serum [14], urine [15], and CSF. [15]

### Reference Interval

**Reference Interval for GLU**

| | Conv. Units (mg/dL) | SI Units (mmol/L) | Alternate Units (g/L) |
|---|---|---|---|
| **Serum** | | | |
| Fasting adults | 74–106 | 4.1–5.9 | 0.7–1.1 |

**Reference Interval for GLU**

| | Conv. Units (mg/dL) | SI Units (mmol/L) | Alternate Units (g/L) |
|---|---|---|---|
| **Urine** | | | |
| Random | < 30 | < 1.7 | < 0.3 |
| 24-hour | <500 mg/day* | <2.8 mmol/day** | <0.5 g/day*** |
| **CSF** | 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) = mmol/day.

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

Each laboratory should confirm the validity of these intervals for the population it serves.

### Reporting Units and Unit Conversion

The VITROS Chemistry System may be programmed to report GLU results in conventional, SI, and alternate units.

**Reporting Units and Unit Conversion for GLU**

| 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

### Known Interferences

***Serum and Plasma***

- In fresh specimens, catalase released from the lysis of red blood cells causes a negative bias in glucose results. The degree of bias is proportional to the degree of hemolysis. In fresh samples, a negative bias of up to 10% may be observed with a level of hemolysis associated with a hemoglobin concentration of 250 mg/dL (2.5 g/L).

**NOTE:** Catalase activity decreases with sample storage. Aged samples that are hemolyzed may exhibit a positive bias of up to 10% due to the spectral interference of hemoglobin. Therefore, the magnitude and direction of bias observed with hemolyzed specimens will vary due to the level of catalase activity and concentration of hemoglobin present in the sample.

- Elevated lipids may limit diffusion of oxygen to the reactants. Dilute grossly lipemic samples twofold before analysis.

The VITROS GLU Slide method was screened for interfering substances following NCCLS Protocol EP7. [16] The substances listed in the table, when tested at the concentrations indicated, caused the bias shown.

For substances that were tested and did not interfere, refer to “Specificity.”

**Known Interfering Substances for GLU**

| Interferent* | Interferent Concentration | | Glucose Concentration | | Average Bias | |
|---|---|---|---|---|---|---|
| | | | Conv. (mg/dL) | SI (mmol/L) | Conv. (mg/dL) | SI (mmol/L) |
| **Serum and Plasma** | | | | | | |
| Total protein | 5 g/dL | (50 g/L) | 100 | 5.55 | -5 | -0.28 |
| | 10 g/dL | (100 g/L) | 100 | 5.55 | +6 | +0.33 |
| **Urine** | | | | | | |
| Boric Acid with sodium formate | 10 g/dL | (1617 mmol/L) | 36 | 2.00 | +15% | +15% |
| | 5 g/dL | (735 mmol/L) | | | | |
| 10% Thymol | 5 mL/1.5 L | (5 mL/1.5 L) | 40 | 2.22 | -15% | -15% |
| Sodium fluoride | 10 mg/mL | (238 mmol/L) | 30 | 1.66 | +9% | +9% |
| **CSF** | | | | | | |
| Hemoglobin | 150 mg/dL | (1.5 g/L) | 65 | 3.61 | +5% | +5% |

* 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

Certain drugs and clinical conditions are known to alter glucose concentrations *in vivo*. For additional information, refer to one of the published summaries. [17, 18]

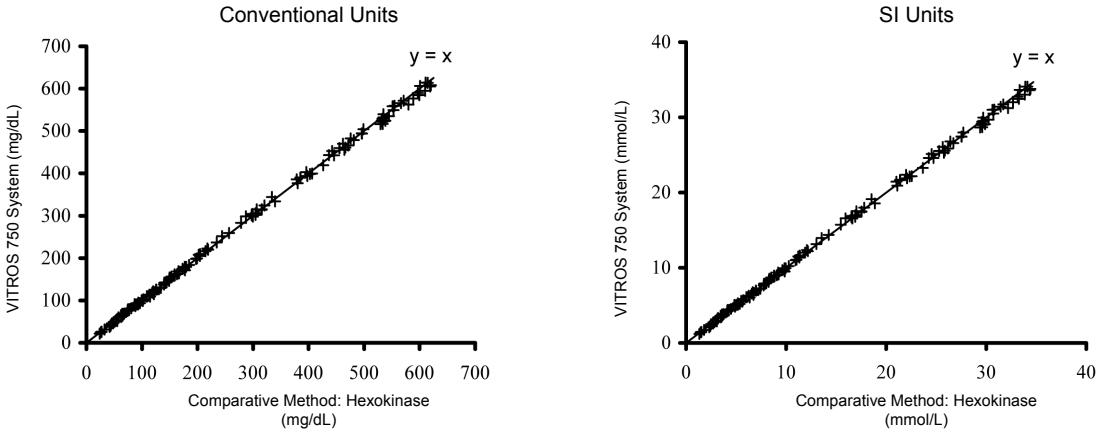
# Performance Characteristics

## Method Comparison

The plots and tables show the results of a comparison of samples analyzed on the VITROS 750 System with those analyzed using the Hexokinase comparative method. [19] Testing followed NCCLS Protocol EP9. [20]

The tables also show the results of comparisons between the VITROS 750 System and a commercially available method, comparisons of the VITROS 250 and 950 Systems with the VITROS 750 System, and comparisons of the VITROS 5,1 FS System with the VITROS 950 System.

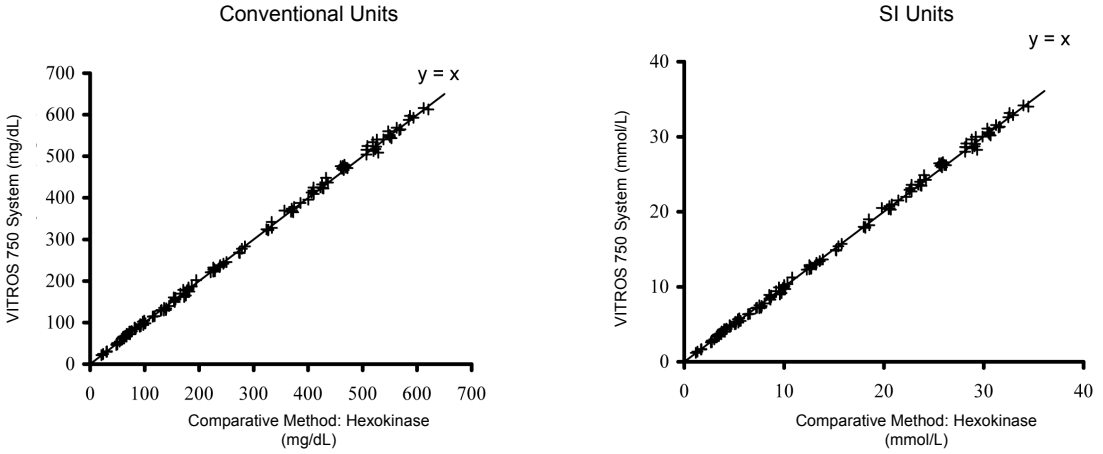
### Method Comparison for GLU: Serum




### Method Comparison for GLU: Serum

| | n | Slope | Correlation Coefficient | Conventional Units (mg/dL) Range of Sample Conc. | Intercept | Sy.x | SI Units (mmol/L) Range of Sample Conc. | Intercept | Sy.x |
|---|---|---|---|---|---|---|---|---|---|
| **750 System vs. comparative method** | 145 | 0.99 | 1.000 | 24–620 | +1.64 | 5.12 | 1.3–34.4 | 0.09 | 0.28 |
| **250 System vs. 750 System** | 55 | 1.00 | 1.000 | 64–604 | +0.06 | 3.44 | 3.6–33.5 | 0.00 | 0.19 |
| **950 System vs. 750 System** | 126 | 0.99 | 0.999 | 28–616 | +0.02 | 1.72 | 1.6–34.2 | 0.00 | 0.10 |
| **5,1 FS System vs. 950 System** | 119 | 1.01 | 1.000 | 23–561 | -0.01 | 1.75 | 1.3–31.1 | 0.00 | 0.10 |

### Method Comparison for GLU: Urine



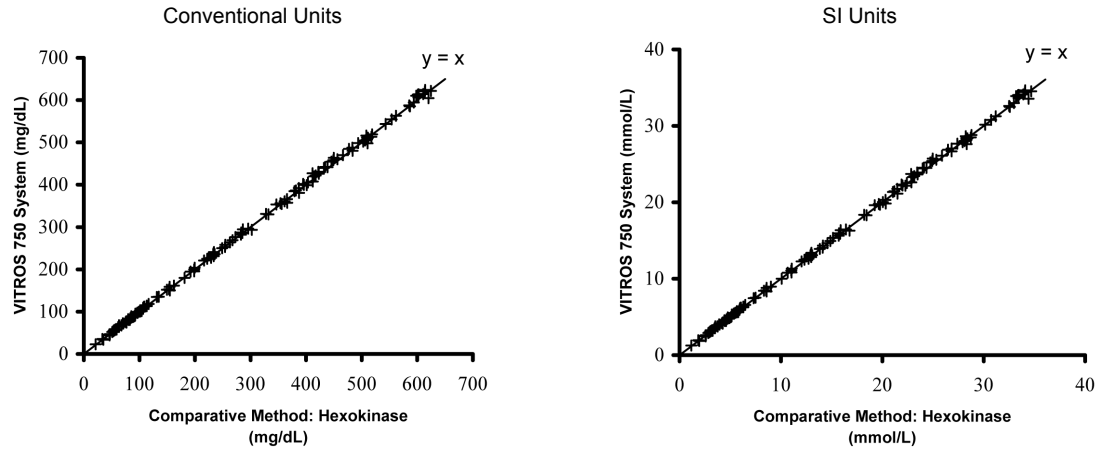
**Method Comparison for GLU: Urine**

| | | | | Conventional Units (mg/dL) | | | SI Units (mmol/L) | | |
|---|---|---|---|---|---|---|---|---|---|
| | n | Slope | Correlation Coefficient | Range of Sample Conc. | Intercept | Sy.x | Range of Sample Conc. | Intercept | Sy.x |
| **750 System vs. comparative method** | 145 | 1.00 | 1.000 | 21–621 | -0.18 | 5.81 | 1.2–34.5 | -0.01 | 0.32 |
| **250 System vs. 750 System** | 43 | 1.03 | 0.999 | 21–627 | -3.33 | 6.98 | 1.1–34.8 | -0.18 | 0.39 |
| **950 System vs. 750 System** | 100 | 1.00 | 0.999 | 25–561 | +0.23 | 1.42 | 1.4–31.1 | +0.01 | 0.08 |
| **5,1 FS System vs. 950 System** | 102 | 1.00 | 1.000 | 24–646 | -2.33 | 2.16 | 1.3–35.9 | -0.13 | 0.12 |
| **750 System vs. commercial method*** | 83 | 0.89 | 0.994 | 36–748 | -3.66 | 21.91 | 2.0–41.5 | -0.20 | 1.22 |

* Boehringer Mannheim Glucose/HK (Hitachi 747)

***CSF***

**Method Comparison for GLU: CSF**




**Method Comparison for GLU: CSF**

| | | | | Conventional Units (mg/dL) | | | SI Units (mmol/L) | | |
|---|---|---|---|---|---|---|---|---|---|
| | n | Slope | Correlation Coefficient | Range of Sample Conc. | Intercept | Sy.x | Range of Sample Conc. | Intercept | Sy.x |
| **750 System vs. comparative method** | 143 | 1.00 | 1.000 | 21–625 | +0.32 | 4.27 | 1.2–34.7 | +0.02 | 0.24 |
| **250 System vs. 750 System** | 38 | 1.01 | 1.000 | 21–521 | -1.14 | 5.09 | 1.2–28.9 | -0.06 | 0.28 |
| **950 System vs. 750 System** | 102 | 1.00 | 0.999 | 21–593 | +0.06 | 1.48 | 1.2-–32.9 | 0.00 | 0.08 |
| **5,1 FS System vs. 950 System** | 105 | 1.00 | 1.000 | 20–550 | -0.75 | 1.93 | 1.1–30.5 | -0.04 | 0.11 |
| **750 System vs. commercial method*** | 94 | 0.96 | 1.000 | 29–549 | +1.77 | 4.85 | 1.6–30.5 | +0.10 | 0.27 |

* Boehringer Mannheim Glucose/HK (Hitachi 747)

## Precision

Precision was evaluated with quality control materials on VITROS 250, 750, 950, and 5,1 FS Systems following NCCLS Protocol EP5. [21]

The data presented are a representation of test performance and are provided as a guideline. Variables such as sample handling and storage, reagent handling and storage, laboratory environment, and system maintenance can affect reproducibility of test results.

### Precision for GLU: 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 750 | 81 | 0.5 | 0.7 | 4.5 | 0.03 | 0.04 | 0.9 | 91 | 23 |
| | 99 | 0.5 | 0.9 | 5.5 | 0.03 | 0.05 | 0.9 | 92 | 23 |
| | 268 | 1.7 | 2.3 | 14.9 | 0.09 | 0.13 | 0.9 | 92 | 23 |
| 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 |
| VITROS 5,1 FS | 83 | 0.4 | 1.2 | 4.6 | 0.02 | 0.07 | 1.5 | 85 | 21 |
| | 292 | 1.1 | 3.5 | 16.2 | 0.06 | 0.20 | 1.2 | 88 | 22 |

* 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.

### Precision for GLU: 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 750 | 50 | 0.3 | 0.4 | 2.8 | 0.02 | 0.02 | 0.8 | 92 | 23 |
| | 304 | 1.3 | 2.2 | 16.9 | 0.07 | 0.12 | 0.7 | 92 | 23 |
| VITROS 950 | 50 | 0.3 | 0.3 | 2.8 | 0.02 | 0.02 | 0.7 | 93 | 23 |
| | 308 | 2.0 | 3.1 | 17.1 | 0.11 | 0.17 | 1.0 | 92 | 23 |
| VITROS 5,1 FS | 26 | 0.2 | 0.3 | 1.5 | 0.01 | 0.02 | 1.2 | 88 | 22 |
| | 291 | 2.1 | 3.9 | 16.1 | 0.11 | 0.22 | 1.3 | 90 | 22 |

* 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.

### Precision for GLU: 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 | 0.3 | 0.9 | 2.3 | 0.02 | 0.05 | 2.2 | 80 | 20 |
| | 85 | 0.7 | 1.8 | 4.7 | 0.04 | 0.10 | 2.1 | 80 | 20 |
| VITROS 750 | 48 | 0.3 | 0.4 | 2.6 | 0.02 | 0.02 | 0.9 | 92 | 23 |
| | 90 | 0.6 | 0.7 | 5.0 | 0.03 | 0.04 | 0.8 | 92 | 23 |
| 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 |
| VITROS 5,1 FS | 38 | 0.2 | 0.4 | 2.1 | 0.01 | 0.02 | 1.0 | 89 | 22 |
| | 82 | 0.5 | 1.1 | 4.5 | 0.03 | 0.06 | 1.4 | 90 | 22 |

* 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.

### Specificity

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

- Toluene (1.3 mL/L)
- Boric acid (5.2 g/L)

The substances listed in the table were tested with VITROS GLU Slides following NCCLS Protocol EP7 [16] and found not to interfere, bias <4.4 mg/dL (<0.24 mmol/L) at the concentration shown.

**Substances That Do Not Interfere With GLU**

| Compound | Concentration | |
|---|---|---|
| Acetaminophen | 5 mg/dL | 331 μmol/L |
| Acetylsalicylic acid | 30 mg/dL | 1665 μmol/L |
| *p*-Aminosalicylic acid | 23 mg/dL | 1718 μmol/L |
| Ascorbic acid | 3 mg/dL | 170 μmol/L |
| Bilirubin | 40 mg/dL | 684 μmol/L |
| Chlorothiazide | 3 mg/dL | 101 μmol/L |
| Creatinine | 15 mg/dL | 1326 μmol/L |
| Dextran | 1000 mg/dL | 250 μmol/L |
| Ethanol | 300 mg/dL | 65 mmol/L |
| Fructose | 30 mg/dL | 1665 μmol/L |
| Galactose | 60 mg/dL | 3330 μmol/L |

| Compound | Concentration | |
|---|---|---|
| Gentisic acid | 0.5 mg/dL | 32 μmol/L |
| Hypaque | 500 mg/dL | 8.2 mmol/L |
| Intralipid | 800 mg/dL | 8 g/L |
| Iodide | 2 mEq/L | 2 mEq/L |
| Isoniazid | 0.4 mg/dL | 29 μmol/L |
| L-dopa | 0.6 mg/dL | 30 μmol/L |
| 6-Mercaptopurine | 1.5 mg/dL | 99 μmol/L |
| Sulfathiazole | 6 mg/dL | 235 μmol/L |
| Tyrosine | 24 mg/dL | 1325 μmol/L |
| Urea nitrogen | 100 mg/dL | 36 mmol/L |
| Xylose | 25 mg/dL | 1666 μmol/L |

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## Glossary of Symbols

The following symbols may have been used in the labeling of this product.

| | | | | | |
|---|---|---|---|---|---|
|  | Do Not Reuse |  | Upper Limit of Temperature |  | This end up |
|  | Use by or Expiration Date (Year-Month-Day) |  | Lower Limit of Temperature | SI | SI Units |
| LOT | Lot Number |  | Temperature Limitation | CONV | Conventional Units |
| SN | Serial Number |  | Consult Instructions for Use |  | Value |
| REF | Catalog Number or Product Code |  | Irritant |  | Range |
|  | Attention: See Instructions for Use |  | Harmful |  | Range of Means |
|  | Manufacturer |  | Toxic |  | Midpoint |
| EC REP | Authorized Representative in the European Community |  | Fragile, Handle with Care |  | Revised |
|  | Contains Sufficient for "n" Tests |  | Keep Dry |  | Supersedes |
| IVD | *In vitro* Diagnostic Medical Device |  | Der Grüne Punkt (the Green Dot). Manufacturer follows certain packaging material waste disposal management regulations | σ | Estimate within-lab SD |

## Revision History

| Date of Revision | Version | Description of Technical Changes* |
|---|---|---|
| 2004-09-13 | 4.0 | • Added VITROS 5,1 FS Chemistry System<br>• Known Interfering Substances – added CSF (Hemoglobin)<br>• Specificity – added intralipid; updated bilirubin<br>• Glossary of Symbols – updated data |
| 2003-07-28 | 3.0 | • Slide Storage and Stability – added the Specimen Type Used column; updated storage values for both unopened and opened cartridges<br>• Reference Interval – Serum: corrected the SI value to 4.1 mmol/L<br>• Limitations of the Procedure – Serum and Plasma: updated data for hemolysis<br>• References – added 14 |
| 2002-12-16 | 2.0 | • New organization and sections consistent with IVD Directive<br>• Reference Interval – serum: replaced data with that for fasting adults<br>• Limitations of the Procedure – serum: updated hemoglobin interference; urine: updated interferents<br>• Method Comparison – serum: updated all comparisons; urine and CSF: updated all except for 950 vs. 750 Systems; updated all plots<br>• Precision – serum: updated 750 system; urine: updated 750 and 950 Systems; CSF: updated 250 and 750 Systems<br>• Specificity – added toluene and boric acid as preservatives that do not interfere<br>• References – added 4, 5, 10, 12, 14, 16, 21 |
| 2002APR19 | 1.0 – English only | New format, technically equivalent to 11/96. |

* The change bars indicate the position of a technical amendment to the text with respect to the previous version of the document.

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

CE

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