

PRINCIPLE:

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. The chemistry of the glucose slides has been described by Curme, et al.

For further details, see individual method sheet for details in the VITROS "Instructions for Use Manual".

SCOPE:

Medical Technologists and Medical Laboratory Technicians

SPECIMEN REQUIREMENTS:

- 1. Body Fluid received in a Red Top Spin specimen for 10 minutes and transfer supernate. Hemolyzed specimens should not be used. Hemoglobin is a protein and its presence in the body fluid will result in an increase in measured protein.
- 2. Specimens are retained in the stoppered containers for 7 days in the specimen refrigerator. Specimens are stable for 3 days at 2-8 degrees C; room temperature 18-28 degrees C for 4 hours or less; frozen at -18 degrees C for six (6) months.

EQUIPMENT AND MATERIALS:

- VITROS GLU Slides
- VITROS Calibrator Kit 1
- Quality Control Materials, 3 levels (see Quality Control Material Procedure)
- VITROS Chemistry Products 7% BSA

REAGENTS:

Reactive ingredients: 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.

Written: J. Scherer 8/13 Revised: Cartridge Handling, Storage and Stability:

- 1. Warm at room temperature 60 minutes in the foil wrapper before putting on the instrument.
- 2. Store unopened frozen at -18 degrees C or lower stable until expiration date.
- 3. Stable on instrument for one (1) week. Turned off, 2 hours.
- **4.** GLU Slides are stable until the expiration date on the carton when they are stored and handled as specified.
- 5. Note: Do not use slide cartridges with damaged or incompletely sealed packaging. Inspect the packaging for damage and use caution when opening to avoid damaging package.
- 6. Unwrap and load the cartridge into the Vitros slide supply.

CALIBRATION:

1 VITROS Chemistry Calibration Kit 1.

2 Store unopened – frozen at -18degrees C or below.

3 Store reconstituted at 2-8 degrees C. Stable 24 hours.

See Calibration section of VITROS Operations Manual.

QUALITY CONTROL:

For Quality Control Procedure and Materials used, Reporting Ranges and other operational details, see that section of the Vitros procedure manual.

PROCEDURE:

Instrument Operating Instructions:

Refer to the operating instructions for the VITROS 350 Chemistry System.

**IMPORTANT:

Bring all fluids and samples to room temperature, 18°.28°C, prior to analysis.

Sample Dilution

If BF glucose concentrations exceed the system's measurement range. **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 samples BF glucose concentration.

REPORTING RESULTS: Results are transmitted to the LIS and if necessary, may be reported directly from the Vitros printout

REFERENCE RANGE:

Reference ranges have not been established for this assay.

LIMITATIONS OF THE PROCEDURE:

• 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).

DISTRIBUTION:

1 KP Laboratory Website - Policies and Procedure - MOL Chemistry Section

2 Regional Reference Laboratory - QA Manager Document Control

REFERENCES:

1. Tietz NW (Ed). Fundamentals of Clinical Chemistry. ed. 3. Philadelphia: WB Saunders; 328.329; 1987.

2. Corcoran RM, Durnan SM. Albumin Determination by a Modified Bromcresol Green Method. *Clin. Chem.* 23(4):765; 1977.

3. Tietz NW. Textbook of Clinical Chemistry. Philadelphia: WB Saunders; 589; 1986.

4. Young DS. Effects of Drugs on Clinical Laboratory Tests. ed. 4. Washington D.C.: AACC

5. VITROS GLU Slides Test Methodology sheet.