KAISER PERMANENTE®
COLORADO LABORATORY

BF Protein - VITROS 350

PRINCIPLE:

The VITROS PROT Slide is a multilayered, analytical element coated on a polyester support. The analysis is based on a modification of the biuret reaction. A drop of patient sample is deposited on the slide and is evenly distributed by the spreading layer to the underlying layers. Protein in the sample forms a complex with cupric ion and results in the dissociation of the cupric ion from the copper–azo dye complex. The decrease of the copper–azo dye complex is measured by reflectance spectrophotometry and is proportional to the concentration of proteins in the sample. For further details, see individual method sheet 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 PROT Slides
- VITROS Calibrator Kit 5
- Quality Control Materials, Levels 1 and 2 Vitros Liquid Performance Material (see Quality Control Material Procedure)
- VITROS isotonic saline
- VITROS Chemistry Products FS Diluent Pack 2 (BSA/Saline) (for on-analyzer dilution)
- Sample cups

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Revised:

REAGENTS:

1. **Slide Ingredients:** Cupric cyclohexanebutyrate 12 µg; phenylazo pyridinol (dye) 9 µg; and lithium hydroxide 350 µg.
2. ***Inactive ingredients:*** Polymer beads, binders and surfactants.

Cartridge Handling, Storage and Stability:

1. **Warm at room temperature for 60 minutes when taken from the freezer in the foil wrapper before putting on the instrument.**
2. **Store frozen at -18 degrees C or below.**
3. **Stable on instrument for one (1) week.**
4. PROT 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 5.
2 Store unopened – frozen at -18degrees C or below.
3 Store reconstituted at 2-8 degrees C. Stable for 24 hr.

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.

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Revised:

Sample Dilution
If BF Protein concentration exceeds the system's measurement range: *
Manual Sample Dilution

1. Dilute the sample with isotonic saline.
2. Reanalyze.
3. Multiply the results by the dilution factor to obtain an estimate of the original sample's BF Protein.

On-Analyzer dilution
Not recommended

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:
Interfering substances:

Interferent *	Interferent Concentration		CSF Protein Concentration		Average Bias	
			Conv. (mg/dL)	SI (mg/L)	Conv. (mg/dL)	SI (mg/L)
Ampicillin **	10 mg/dL	(286 µmol/L)	50	500	21.0	210
Ascorbic acid	3 mg/dL	(170 µmol/L)	50	500	13	130
Bilirubin	5 mg/dL	(86 µmol/L)	58	580	13.7	137
Dextran	500 mg/dL	(5000 mg/L)	50	500	48	480
Mannitol	1000 µg/mL	(5.4 mmol/L)	50	500	12	120
Salicylic acid	35 mg/dL	(2530 µmol/L)	50	500	27	270
	50 mg/dL	(3620 µmol/L)	50	500	31	310
Vancomycin **	10 mg/dL	(69 µmol/L)	50	500	13.5	135

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. Tietz NW. *Textbook of Clinical Chemistry*. Philadelphia: WB Saunders; 589; 1986.
3. Young DS. *Effects of Drugs on Clinical Laboratory Tests*. ed. 4. Washington D.C.: AACC
4. VITROS PROT Slides Test Methodology sheet.

Written: J. Scherer 8/13
Revised: