KAISER PERMANENTE®
COLORADO LABORATORY

DIGOXIN - VITROS 350

PRINCIPLE:

The VITROS DGXN 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. Digoxin in the sample competes with the digoxin-peroxidase conjugate for a limited number of antibody binding sites during Incubation 1. The subsequent addition of 12 µL of VITROS Immuno-Wash Fluid to the slide removes unbound digoxin-peroxidase conjugate from the read area, while also providing a substrate for the enzyme-mediated oxidation of leuco dye.

The rate of dye formation, as monitored by reflectance spectrophotometry during Incubation 2, is inversely proportional to the digoxin concentration in the sample. To determine if an adequate wash has occurred, a wash detection dye is read at 540 nm during Incubation 2.For further details, see individual method sheet in the VITROS "Instructions for Use Manual".

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SCOPE:

Medical Technologists and Medical Laboratory Technicians

SPECIMEN REQUIREMENTS:

1 Serum
2 Specimens are retained in stoppered containers for one (1) week in the specimen refrigerator. Specimens are stable for one week at 2-8 degrees C; room temperature 18-28 degrees C up to 8 hours; frozen at -18 degrees C for up to 4 months.

Digoxin specimens should be drawn at least six to eight hours after the last dose. [6] If toxicity is suspected, specimens may be drawn at any time.

EQUIPMENT AND MATERIALS:

- VITROS Chemistry Products DGXN Slides
- VITROS Chemistry Products Calibrator Kit 9
- Quality control materials, 3 levels (see Quality Control Material Procedure).
- VITROS Chemistry Products 7% BSA
- VITROS Chemistry Products Immuno-Wash Fluid
- VITROS Chemistry Products FS Diluent Pack 2 (BSA/Saline) (for on-analyzer dilution)
- Sample cups

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Revised:

REAGENTS:

Slide Ingredients:

1. ***Active Ingredients:*** Immobilized mouse monoclonal anti-digoxin antibody 0.01 mg; digoxin-horseradish peroxidase conjugate 0.60 ng; and 2-(3,5-dimethoxy-4-hydroxyphenyl)-4,5-bis(4-dimethylaminophenyl) imidazole (leuco dye) 0.02 mg.
2. ***Inactive ingredients:*** Polymer beads, binders, buffer, and surfactants.

Cartridge Handling, Storage and Stability:

1. **Warm at room temperature 60 minutes 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. DGXN 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 9.
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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Sample Dilution
If Digoxin concentration exceeds the system's measurement range: *
Manual Sample Dilution

1. Dilute the sample with VITROS 7% BSA. An initial twofold dilution is recommended.
2. Reanalyze.
3. Multiply the results by the dilution factor to obtain an estimate of the original sample's digoxin concentration

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:
Therapeutic Range: 0.8-2.0 ng/mL

LIMITATIONS OF THE PROCEDURE:
Interfering substances:

Interferent *	Interferent			Digoxin Concentration		Bias **	
	Concentration		Comments	Conv. (ng/mL)	SI (nmol/L)	Conv. (ng/mL)	SI (nmol/L)
Gentisic Acid	5.0 mg/dL	(0.32 mmol/L)	Therapeutic	2.0	2.6	+0.45	+0.58
N-acetylcysteine	90.0 mg/dL	(5.50 mmol/L)	Upper Therapeutic IV	2.0	2.6	+1.11	+1.42
Bilirubin (conjugated)	20.0 mg/dL	(0.34 mmol/L)		2.0	2.6	+0.54	+0.69
Hemoglobin	300.0 mg/dL	(3 g/L)		2.0	2.6	-0.56	-0.72

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 DGXN Slides Test Methodology sheet.

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