KAISER PERMANENTE®
COLORADO LABORATORY

Creatine Kinase - VITROS 350

PRINCIPLE:

The VITROS CK 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. This layer also contains *N*-acetylcysteine (NAC) to activate CK without pretreating the sample. When the sample is deposited on the slide, creatine kinase catalyzes the conversion of creatine phosphate and ADP to creatine and ATP. In the presence of glycerol kinase (GK), glycerol is phosphorylated to L-α-glycerophosphate by ATP. Oxidation of L-α-glycerophosphate to dihydroxyacetone phosphate and hydrogen peroxide occurs in the presence of L- α -glycerophosphate oxidase (α-GPO). Finally, leuco dye is oxidized by hydrogen peroxide in the presence of peroxidase to form a dye. Reflection densities are monitored during incubation. The rate of change in reflection density is then converted to enzyme activity.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 or Heparinized plasma (note: lithium heparin sample required if running as a panel with electrolytes)
2. Specimens are retained in stoppered containers for 5 days in the specimen refrigerator. Specimens are stable for 5 days at 2-8 degrees C; room temperature 18-28 degrees C for 4 hours or less; frozen at -18 degrees C for one (1) month.

EQUIPMENT AND MATERIALS:

- VITROS CK Slides
- VITROS Calibrator Kit 3
- Quality Control Materials, 3 Levels (see Quality Control Material Procedure)
- VITROS Chemistry Products 7% BSA
- VITROS Chemistry Products FS Diluent Pack 2 (BSA/Saline) (for on-analyzer dilution)
- Sample cups

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Revised:

REAGENTS:

1. ***Slide Ingredients*:** L-alpha-glycerophosphate oxidase (*Aerococcus viridans*, E.C.1.1.3.21) 0.4 U; peroxidase (horseradish root, E.C.1.11.1.7) 1.4 U; glycerol kinase (*E.coli*, E.C.2.7.1.30) 0.5 U; creatine phosphate 170 µg; N-acetylcysteine 54 µg; magnesium acetate 20 µg; glycerol 20 µg; 2-(3,5-dimethoxy-4-hydroxyphenyl)-4,5-bis-(4-dimethylaminophenyl) imidazole (leuco dye) 20 µg and adenosine diphosphate 20 µg.
2. ***Inactive ingredients:*** Pigment, binder, buffers, surfactants, inhibitors, stabilizers, cross-linking agent, dye solubilizer, scavenger and chelator.

Cartridge Handling, Storage and Stability:

1. **Warm at room temperature for 30 minutes when taken from the refrigerator or 60 minutes 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. CK 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 3.
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

Serum and Plasma

If CK 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 creatine kinase activity.
4.

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:

Females	30–135 U/L
Males	55–170 U/L

LIMITATIONS OF THE PROCEDURE:

Interfering substances:

Carbon dioxide at a level of 40 mmol/L may cause up to a 30% negative bias in creatine kinase.

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 CK Slides Test Methodology sheet.

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