

Manufacturer and Product Information

Mission Diagnostics
 A Division of Diamond Diagnostics, 333 Fiske Street, Holliston, MA.
For Technical Assistance call:
 Diamond Diagnostics Technical Services at 1-508-429-0450

Intended Use: 634 Ca⁺⁺/ pH Cal-Pak: To provide calibration points for the Ca⁺⁺ and pH electrodes.
 Deproteinizer Kit: To remove protein build-up from the sample flow path.
 Conditioner Kit: To clean and condition the pH electrode.

Summary And Principle: This product is intended to serve as a functional equivalent to pre-existing material distributed by the Original Equipment Manufacturer (OEM). Diamond Diagnostics calibrators have defined electrolyte concentrations that provide internal calibration points against which samples are measured by direct Ion Selective Electrode Methods.

Reagents: 634 Cal-Pak CD-478548AD (contents at 37°C), Deproteinizer; Conditioner
Containing:
634 Cal-Pak CD-478548AD: Ca⁺⁺/pH Flush Solution is an aqueous solution containing: 1.25 mmol/L Ca⁺⁺, pH 6 -8 Tris buffer, NaCl, surfactant, and preservative.
 Ca⁺⁺/pH Cal Standard is an aqueous solution containing: 1.25 mmol/L Ca⁺⁺, pH 7.38 MOPS buffer, NaCl, surfactant and preservative.
Deproteinizer Solution: A contains NaCl, KCl, CaCl, LiCl, HCl, preservative; B contains active pepsin
Conditioner: NH₄HF₂
 For *in vitro* diagnostic use only

Values Assignment: Each calibration standard is tested for each calibrating analyte. Reference is made to either an aqueous standard made with corresponding analyte NIST (National Institute of Standards and Technology) material or the OEM Calibrator.

Cautions: Exercise normal laboratory precautions. If contact occurs with skin, rinse affected area with water. If contact with eyes occurs, immediately rinse with copious amount of clean water or eye rinse. In cases of accidental ingestion, contact a physician immediately.

Stability: Package stability (expiration date) is listed on the product label. Do not use open or closed reagent beyond this date. Store upright at room temperature, 18°-25 °C.

Procedure

Procedure: The Cal-Paks and Conditioner are manufactured in a ready to use form. The Deproteinizer requires preparation as directed by the instructions on the product label. All are intended to serve as a direct replacement to pre-existing materials distributed by the OEM. For a detailed description of the use of this material, refer to the Instrument Operator's Manual.

Quality Control: Diamond Diagnostics suggests the use of commercially available control material with results assayed for the instrument used. Controls should be run at Normal and Abnormal levels. Diamond Diagnostics suggests measuring controls before patient samples are run and following instrument maintenance.

Limitations

Limitations: If the instrument fails calibration or controls do not measure within acceptable range when Diamond Diagnostics products are used, Diamond Diagnostics suggests the following:

Verify that the internal calibrators used to standardize the instrument are correct for the instrument, have adequate expiration, and do not contain visually evident contamination.

Follow the procedures delineated within the Operator's Manual listed under Troubleshooting.

Ensure that all appropriate Maintenance Procedures, as listed in the Operator's Manual, have been performed.

If problems still exist, contact Diamond Diagnostics' Technical Service Department.

