

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: To provide calibration of Na⁺, K⁺, Cl⁻, and tCO₂ on the Dimension® system.

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

Reagents: ISE Standard C, DA-D100D 27 mL or DA-D200D 90mL
Containing: ISE Standard C, is an aqueous solution containing 140 mmol/L Na⁺, 4.0 mmol/L K⁺, 121 mmol/L Cl⁻, 18 mmol/L tCO₂, and preservative. [DA-D202D is a larger volume and can only be used on the Dimension® AR system].

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: Product stability is listed on the product label. The product should not be used beyond this date. Store upright at room temperature, 18°- 25 °C. Product intended for single use.

Procedure

Procedure: The product is manufactured in a ready to use form. It is intended to serve as a direct replacement to pre-existing materials distributed by the OEM. For a detailed description of the use of this reagent, refer to the Instrument's Operator 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.

