

Certificate of Analysis

To Whom It May Concern:

This is to certify that the in-vitro diagnostic products listed below may be marketed in and exported from the United States of America. The manufacturing facility in which the product is produced is subject to periodic inspections by the United States Food and Drug Administration (FDA). The last such inspection demonstrated that the facility was in substantial compliance with quality management requirements for the product.

Information
Manufacturer
Mission Diagnostics a Division of Diamond Diagnostics Inc. 333 Fiske Street Holliston, MA 01746 USA
Product
Part Number: DA-S560D Description: IMT Standard C Filling Volume: 4 x 90 mL Storage: 18-25°C Shelf Life: 2 Years

Details
Function: To provide calibration points for Na ⁺ , K ⁺ Cl ⁻ and tCO ₂ electrodes for Dade Dimension Analyzers.
Quality Specifications: Passed
Reagent Contents: An aqueous solution containing 140.0 mmol/L Na ⁺ , 4.0 mmol/L K ⁺ , 121 mmol/L Cl ⁻ , 18 mmol/L tCO ₂ , preservative and surfactant. For in vitro diagnostic use only.

Certified By:



Kathryn R. Thorsen
 Quality Assurance Manager
 Diamond Diagnostics, Inc.