

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: BK-472095D Description: ISE Electrolyte Buffer Filling Volume: 2000 mL Storage: 18-25°C Shelf Life: 2 Years

Details
Function: For the quantitative determination of Na ⁺ , K ⁺ , Cl ⁻ , total CO ₂ in serum, plasma, urine and cerebrospinal fluid on the Beckman CX Synchron and Delta Systems.
Quality Specifications: Passed
Reagent Contents: An aqueous solution containing 1.5 mmol/ L Tris phosphate buffer. For in vitro diagnostic use only.

Certified By:



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