



Becton Dickinson and Company
 BD Diagnostic Systems
 1475 Athens Highway
 Grayson GA 30017 US

Certificate of Analysis

Product Name : VIAL COAG PLASMA RABBIT EDTA 10X3ML
Catalog Number : 240827 **Manufacture Date** : 2011/01/28
Batch Number : 1027146
Expiration Date : 2014/01/27

Dehydrated Appearance: Off-white to cream, dried button or fluffy material.
 Solubility: Soluble in distilled or deionized water.(per package instructions)
 Rehydrated Appearance: Off-white to cream, opaque solution without visible fibrin.
 Coagulase Test: A fixed amount of Coagulase Plasma was pipetted into one tube per test specimen. 0.5 microliters of an overnight broth culture were added, mixed and incubated at 37 ± 1°C for six hours. Coagulation was examined after two, four and six hours of incubation.

TEST ORGANISMS	ATCC®	COAGULASE REACTION
Staphylococcus aureus	25923	clot (positive)
Staphylococcus aureus	29123	clot (positive)
Staphylococcus epidermidis	12228	no clot (Negative)
Enterobacter aerogenes	13048	no clot (Negative)

Animal Source	Country of Origin	Tissue Category		
		BIC	SIC	ABC
Leporine	USA	IV	IV	B

The Batch Number on this certificate is synonymous with the Lot Number shown on the product label.

BD Diagnostic Systems (BDDS) is an ISO 13485:2003 and ISO 9001:2008 Registered facility. BDDS products are manufactured in facilities registered with the United States Food and Drug Administration (FDA), and are regulated by the FDA's Quality System Regulations (QSRs). This product met BDDS stringent quality standards at time of batch/lot release. Any test results reported on this certificate were obtained at time of release.

BD Diagnostic Systems' Certificates of Analysis (COA) typically are set up to contain animal origin information for finished products manufactured using materials of animal origin. The animal origin information may be contained in the animal source table and/or in one or more of the additional paragraphs found on the COA. This information is a compilation of animal origin data from the individual lots of raw materials used to manufacture the batch of BD Diagnostic Systems (BDDS) finished product for which the COA was created.



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At the time the BDDS Certificate of Analysis is created and sent to the Internet website address at <http://www.bd.com/regdocs/>, the animal origin information as provided to BDDS by its suppliers is pulled into the certificate as it is created by the BDDS automated certificate system.

At times, suppliers notify BDDS of new and/or additional information they have received from their raw material suppliers that modifies the animal origin information for lots previously provided to BDDS. When this situation occurs, BDDS updates the animal origin information in the automated certificate system, recreates the affected finished product COAs for batches within expiration date, and sends them to the Internet website where they replace the prior certificate and are immediately available to customers.

Customers enrolled in BD Diagnostic Systems' Automated Change Notification Program will be notified of the changes described above.

For complete details refer to "BD Position Statement - BD Diagnostic-Diagnostic Systems, COA Animal Origin Information Position Statement", located on the Internet website address at <http://www.bd.com/regdocs/>.

John Gerlich
Vice President,
Quality Management and
Regulatory Compliance
Signature Date: 2011/06/22