

## **Certificate of Analysis**

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Becton Dickinson and Company BD Diagnostic Systems 1475 Athens Highway Grayson GA 30017-1538 US

Product Name : Vial Coag Plasma Rabbit Edta 10X3Ml

Catalog Number : 240827 Manufacture Date :2014/09/05

Batch Number : 4255745 Expiration Date : 2017/09/04

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. 0.05

milliliters of an overnight broth culture was added, mixed

and incubated at 37  $\pm$  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	29213	clot (positive)
Staphylococcus epidermidis	12228	no clot (Negative)
Enterobacter aerogenes	13048	no clot (Negative)

Animal source	Country of	Tissue Category			
	Origin	BIC	SIC	ABC	
Leporine	USA	IV	IV	IB	

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

BD Diagnostics - Diagnostic Systems products are manufactured in ISO 9001:2008 Registered facilities. In addition, BD Diagnostics - Diagnostic Systems facilities are registered with the United States Food and Drug Administration (FDA), are regulated by the FDA's Quality System Regulations (QSRs), and are also ISO 13485:2003 Registered. 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. This material is not for human or animal consumption.

BD Diagnostics - Diagnostic Systems' Certificates of Analysis (COA) typically contain animal origin information when products are manufactured using materials of animal origin. This information may be contained in the animal source table and/or in one or more of the additional paragraphs found on the COA. Following Quality Control release, the COA is created and published at http://www.bd.com/regdocs. For each batch of finished product that contains animal origin raw materials, the COA shows the animal origin data from the individual lots of animal origin raw materials used, as provided by the raw material suppliers.

At times, suppliers notify BD Diagnostics - Diagnostic Systems of new

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and/or additional information they have received from their raw material suppliers that modifies the animal origin information for lots previously provided to BD. See "COA Animal Origin Information Position Statement" located at http://www.bd.com/regdocs under "Position Statements" for the impact that retrospective information has on COAs and on customers enrolled in the BDDS and BDAB Automated Change Notification Program.

For complete details on animal origin information, refer to "BD Position Statement - BD Diagnostic-Diagnostic Systems, COA Animal Origin Information Position Statement", at http://www.bd.com/regdocsunder "Position Statements".

Paula A. Elliott

WW Quality Manager, Media

BD Diagnostics - Diagnostic systems

Signature Date: 2014/10/16

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