

## **Certificate of Analysis**

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

Product Name	: VIAL COAG PLASMA	. RABBIT EDTA 10X3ML
Catalog Number :	: 240827	Manufacture Date : 2013/01/28
Batch Number :	: 3035480	
Expiration Date :	: 2016/01/28	

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 ± 1°C for six hours. Coagulation was examined after two, four and six hours of incubation.

Country of		Tissue Category			
	Staphylococcus Staphylococcus Enterobacter ad	epidermidis	29213 12228 13048	clot (positive) no clot (Negative) no clot (Negative)	
	Staphylococcus		25923	clot (positive)	

	Country of	Tissue (	Category		
Animal Source	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



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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 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/regdocs under "Position Statements".

Paula A. Clast

Paula A. Elliott WW Quality Manager, Media BD Diagnostics - Diagnostic Systems Signature Date: 2013/03/05