



# Certificate of Analysis

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** : 2016/12/28  
**Batch Number** : 6358789  
**Expiration Date** : 2019/12/28

Lyophilized 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°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 Origin	Tissue Category		
		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



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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".

Manufacturer is Becton Dickinson and Company, 7 Loveton Circle, Sparks, MD 21152 USA. To determine location of manufacturing for this product, please see [www.bd.com/ds/technicalCenter/regulatory.asp](http://www.bd.com/ds/technicalCenter/regulatory.asp).

Charlotte Dannenfelser  
BD Life Sciences - Diagnostic Systems  
Quality Director, Microbiology  
Signature Date: 2017/01/23