



Rocky Mountain Biologicals, Inc

Certificate of Analysis

Bovine Fibrinogen- US Origin

Product Number: BFB-BDG-01G BFB-BDG-01K Lot Number: 20160919FB
 BFB-BDG-05G BFB-BDG-SMP Date of Manufacture: 09/2016
 BFB-BDG-10G BFB-BDG-CSP Expiration Date: 09/2018
 BFB-BDG-25G Storage Temperature: ≤ -10° C
 BFB-BDG-1XG



BASIS FOR RELEASE NOT FOR HUMAN OR ANIMAL CONSUMPTION

CHEMICAL ANALYSIS			
TEST	METHOD	SPECIFICATION	RESULT
<small>Tests performed in 4% solution unless otherwise noted</small>			
Appearance	Visual	White to Off-White Powder	Pass
Chloride	Chemistry Analyzer	As Reported	38 mEq/L
Clottable Protein (%)	Colorimetric	≥ 75%	88 %
Moisture	Karl Fischer	≤ 10%	7.12 %
pH	pH Meter	6.0 - 8.0	7.1
Potassium	Chemistry Analyzer	As Reported	< 1 mEq/L
Purity	SDS PAGE	≥ 90%	99%
Sodium	Chemistry Analyzer	As Reported	85 mEq/L
Total Protein	Chemistry Analyzer	70 - 95%	78 %

Solubility: 1-4% soluble in water, saline or PBS

STATEMENT OF ORIGIN

Raw serum used in the manufacture of this product was obtained from approved suppliers collecting from abattoirs in the United States from traceable animals originating from the United States. Full health, traceability, and required regulatory documentation are maintained under RMBIO's quality systems. The serum was processed, filtered, and finished in the United States.

BSE/TSE STATEMENT

The United States of America is recognized as having negligible BSE/TSE risk by the World Organization for Animal Health (OIE).

ISIA CERTIFICATE TRACEABILITY

All raw serum is certified by the International Serum Industry Association (ISIA) to be sourced in accordance with their strict guidelines. (www.serumindustry.org).

EUROPEAN UNION ELIGIBILITY

Product meets European Union requirements for production of technical blood products.

Approval

Quality Assurance- Print Name: Terri Sorensen	Quality Assurance- Sign Name: 	Date: 08 Dec 2016
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