



Rocky Mountain Biologicals, Inc

Certificate of Analysis

Bovine Fibrinogen- US Origin

Product Number: **BFB-BDG-01G** **BFB-BDG-01K** Lot Number: **20160826FB**
BFB-BDG-05G **BFB-BDG-SMP** Date of Manufacture: **08/2016**
BFB-BDG-10G **BFB-BDG-CSP** Expiration Date: **08/2018**
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	144 mEq/L
Clottable Protein (%)	Colormetric	≥ 75%	90.4 %
Microbial	Plate Count	As Reported	8250 CFU/g
Moisture	Loss on Drying	≤ 10%	4.7 %
pH	pH Meter	6.0 - 8.0	7.6
Potassium	Chemistry Analyzer	As Reported	4.5 mEq/L
Purity	SDS PAGE	≥ 90%	99%
Sodium	Chemistry Analyzer	As Reported	191 mEq/L
Total Protein	Chemistry Analyzer	70 - 95%	87.5 %

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

STATEMENT OF ORIGIN

Raw plasma/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 plasma 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).

Approval

Quality Assurance- Print Name: Terri Sorensen	Quality Assurance- Sign Name: 	Date: 30 Sep 2016
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