

CERTIFICATE OF ANALYSIS

Product: CBC-5DMR
Lot Number: BC1805BL, BC1805BN, BC1805BH
Expiration Date: 2018-07-05
Date of Manufacture: (L) 2018-03-22
(N) 2018-03-22
(H) 2018-04-02

Manufactured by: R&D Systems, Inc.
614 McKinley Place NE
Minneapolis, Minnesota 55413 USA

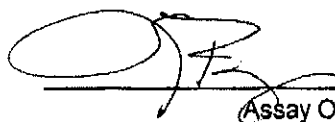
Phone: (612) 379-2956
Fax: (612) 379-6809

Product Characteristics:

This material is a whole blood product and should be similar in appearance to fresh whole blood after mixing. When stored at 2 to 8°C, unopened vials are stable until the expiration date. DO NOT FREEZE.

-  **WARNING: POTENTIAL BIOHAZARDOUS MATERIAL.** For *in vitro* diagnostic use. Each human donor/unit used in the preparation of this product has been tested, and yielded non-reactive / negative results for all conditions referenced in 21 CFR 610.40 (a) (b), as required by the FDA. Testing was conducted using FDA-licensed tests. Additional details can be found at <http://www.rndheme.com/TechnicalInformation.aspx>.
No test method can offer complete assurance that infectious agents are absent; therefore this material should be handled as potentially infectious. When handling or disposing of vials follow precautions for patient specimens as specified in the OSHA Bloodborne Pathogen Rule (29 CFR Part 1910, 1030) or other equivalent biosafety procedures.
- Lot uniformity studies verified product specifications were met and maintained in vial to vial testing.
- Fill volumes were verified.
- Microbiology testing meets specifications. These lots have been tested as per quality control procedures and found free of viable pathogenic or hemolytic microorganisms and fungi. This material is non-sterile.

This product has been manufactured according to all applicable FDA Good Manufacturing Practice regulations. These lots meet Manufacturing and Quality Assurance release specifications and are approved for release to Shipping/Marketing.



Assay Office

2018-04-11

Date

Distribution: Original: Shipping
Copy: Assay Office Product File
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forms\coa-hum\generic.doc
Rev. 8/30/16