bio-techne®

R&D SYSTEMS

CERTIFICATE OF ANALYSIS

Product: CBC-3D

Item Number:

3D2THU	3D2TLU	3D2TNU	3D2VH	3D2VHU	3D2VL
3D2VLU	3D2VN	3D2VNU	3D3SCTH	3D3SCTHU	3D3SCTL
3D3SCTLU	3D3SCTN	3D3SCTNU	3D501	3D502	3D503
3D503RX	3D505T	3D506	3D506US	3D507	3D508
3DSSCTH	3DSSCTHU	3D5SCTL	3D5SCTLU	3D5SCTN	3D5SCTNU
B3D2HU	B3D2LU	B3D2NU	B3D4SCTHU	B3D4SCTLU	B3D4SCTNU
D3D02	D3D04	M3D506	W3D3SCTHU	W3D3SCTLU	W3D3SCTNU
WD1154	WD1154A	WD3DH2	WD3DL2	WD3DN2	

Lot Number: B0226L, B0226N, B0226H

Date of Manufacturing / Bottling Date: 2026-12-05

Date of First Use: 2026-01-20

Expiration Date: 2026-05-05

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.

1. 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.
2. Lot uniformity studies verified product specifications were met and maintained in vial to vial testing.
3. Fill volumes were verified.
4. 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

2025-12-26
Date

Distribution: Original: Shipping
Copy: Assay Office Product File
Save scan to COA folder