

QUALITY CERTIFICATE

Product: Boule Con-Diff Tri-Level

Kit Lot Number: 22501-6K

Product Part Number: 502-012

Kit Expiration Date: 2025-06-02

| Product | Vial Lot Numbers | Manufacture Dates | Expiration Dates |
|-----------------------|------------------|-------------------|------------------|
| Boule Con-Diff Low | 22501-61 | 2025-01-13 | 2025-06-02 |
| Boule Con-Diff Normal | 22501-62 | 2025-01-13 | 2025-06-02 |
| Boule Con-Diff High | 22501-63 | 2025-01-17 | 2025-06-06 |

CDS manufactures the products listed above under the jurisdiction of the US Food and Drug Administration (FDA).

CDS (Clinical Diagnostic Solutions Inc, Plantation, Florida) manufactures the products listed above for Boule Medical AB (Spanga, Sweden).

The above products were manufactured and analyzed in accordance with product specifications and quality control procedures and met all testing requirements.

The following additional information is provided:

1. No microbial contamination was recorded per quality control procedures.
2. Fill volumes were verified to meet all specifications.
3. **Handle as potentially infectious.** The human constituents have tested non-reactive for human Immunodeficiency Virus antibody (HIV), Hepatitis B Surface Antigen (HbsAg) and Hepatitis C Virus antibody (HCV).
4. Lot uniformity studies verified that product specifications were met and were maintained in vial to vial testing.
5. The animals used as donors were healthy and came from an USA APHIS (Animal and Plant Health Inspection System) certified facility.



Quality & Regulatory Department

02-21-2025

Date

