



BGT
BioGenTechnologies
GmbH
Von-Langen-Weg 10
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Certificate of Analysis / Conformity

Product: Diff-o-trol
Lot No.: DI0844L; DI0844N; DI0844H
Exp. Date: 2009-02-05

Manufactured by: BGT BioGenTechnologies.GmbH Phone: 02551/4090
Von-Langen-Weg 10 Fax: 02551/1298
D-48565 Steinfurt

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.

This certifies that the product listed above was manufactured according to all applicable FDA Good Manufacturing Practice regulations. This product has been analyzed according to quality control procedures and meets all testing requirements.

The following information is provided:

1.  **WARNING:**

POTENTIALLY BIOHAZARDOUS MATERIAL. For *in vitro* diagnostic use. Each human donor/unit used in the preparation of this product has been tested by a FDA licensed method/test and found to be negative or non-reactive for the presence of HBsAg, Anti-HCV, NAT testing for HIV-1, HCV (RNA) and HIV-1/2. Each unit is also negative by a serological test for Syphilis (RPR or STS). Because no test method can offer complete assurance that infectious agents are absent, 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 (OSHA 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.

QM-Manager
Günter Keul

2008-10-02
Date

