

Product: Coult-o-trol 5 DIMDI Reg.-Nr.: DE/CA22/1116-12-IVD
Lot No.: 871062, 882062, 863062
Exp. Date: 2012-03-05
Date of Manufacture: 2011-10-11

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

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.

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 human blood. 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 microorganism 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

2011-11-03

Date