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Certificate of Analysis / Conformity

Product: CD-o-trol

Lot No.: *CD128*

Exp. Date: 2009-01-02

Target Specifications - Cell-Dyn 3000 / Coulter XL / BD Facscaliber

Parameter	*Target*
WBC /µL	≥ 3500
Lymphocyte /µL	≥ 700

Refer to the Assay Sheet for assay Mean Values for this lot.

(1) Differential values may need to be modified because of restrictions due to instrument capabilities and/or components. Every effort is made to maintain the relative relationship between the major cell types. Minor leukocyte subpopulations are reported as found.

(2) The MCV value obtained is limited by the availability of human erythrocytes. An MCV specification is considered met when the Low Level MCV is less than the Normal Level MCV and the Normal Level MCV is less than the High Level MCV.

WARNING:

POTENT1ALLY 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.

DECLARATION OF CONFORMITY TO SPECIFICATIONS:
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

2008-11-14
Date