

Product: QBC-o-trol
Lot No.: **Q388-1, Q388-2**
Exp. Date: 2010-01-24

Level	Lot number	Expiration date	Date of manufacture
Level 1	Q388-1	2010-01-24	2009-12-17
Level 2	Q388-2	2010-01-24	2009-12-17

Assay values and expected ranges – see Assay Sheet.

INGREDIENS:

QBC-o-trol contains stabilized mammalian red cells, white cells and simulated platelets in a plasma-like fluid.

**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.

These lots have been tested and found free of viable hemolytic microorganisms and fungi.

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

2009-12-30
Date