

POTENTIAL BIOHAZARDOUS MATERIAL



WARNING: POTENTIAL BIOHAZARDOUS MATERIAL. For in vitro diagnostic use. Each human donor/unit used in the preparation R&D Systems' products has been tested, and yielded non-reactive / negative results, according to FDA guidelines as contained in 21 CFR 610.40(a)(b).

Specifically, a sample from each donation used has been tested by FDA-licensed tests and found nonreactive / negative for:

1. Antibodies to human immunodeficiency virus (anti-HIV 1,2), hepatitis C virus (anti-HCV), and antibodies to *Trypanosoma cruzi* (T cruzi, the causative agent of Chagas disease), and nonreactive for hepatitis B surface antigen (HBsAg)
2. Nucleic acid tests (NAT) for HCV ribonucleic acid (RNA), HIV-1 RNA, HBV deoxyribonucleic acid (DNA) and West Nile virus (WNV) RNA
3. Serologic test for syphilis

Because no test method can offer complete assurance that infectious agents are absent, 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 (29 CFR Part 1910, 1030) or other equivalent biosafety procedures.