

Affidavit for Animal and Human Derived Products Assurance of Sourced Animal Health and HIV and Hepatitis Testing

All products manufactured by R&D Systems, Inc. that contain human materials use only materials that have been tested for HIV, Hepatitis and all currently required FDA tests and contain the following cautionary statement:

Warning: Potentially Biohazardous Material. Each human donor unit used in the preparation of this product has been tested by an 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 (29 CFR Part 1910, 1030) or other equivalent biosafety procedures.

All blood received by R&D Systems has been tested negative for viruses in accordance with FDA regulations. Human derived tissues, organs or bodily fluids from the U.S. have been tested and certificates on file for Alphafo Protein and Alpha 1 Antichymotrypsin (ACT). Human derived tissues, organs or bodily fluids sourced from the U.K. have been tested and certificates on file for Prostate Specific Antigen (PSA). All human derived tissues, organs or bodily fluids are sourced from the United States of America, countries or donors believed to be free of Ebola virus infection.

R&D Systems products may contain cellular components from human and animal sources including bovine, porcine, rat, mouse and avian cells. In some products, non-cellular materials (proteins or antibodies) are obtained from rabbits, mice, rats, goats, pigs, cows, sheep, hamsters, chickens or are recombinantly produced source materials. These non-cellular materials are subsequently highly concentrated and purified before use in the products.

If sourced from the United States, the raw materials are sourced from either USDA and/or FDA inspected establishments. The animals are apparently in good health at the time the materials are collected as judged by onsite veterinarians.

In addition, these products may contain Bovine Serum Albumin (BSA). The sources for this protein certify that it is obtained from USDA inspected establishments in the USA or from establishments in OIE negligible or controlled BSE risk countries.

R&D Systems is a registered Medical Device Establishment under the U.S. Food, Drug and Cosmetic Act; registration number 2182501. R&D Systems is routinely inspected by the FDA. Our *in vitro* diagnostic products are manufactured under the Food and Drug Administration's Good Manufacturing Practices Regulations, they are freely marketed in the U.S., and are in compliance with all U.S. laws and regulations.



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