

# PRODUCT DATA SHEET

## Human Serum, Normal

### Description

Normal human serum (mixed blood groups) is used as a growth supplement for cell culture media and in other research applications. Some human cell lines require the addition of human serum rather than animal serum to grow satisfactorily.

### Donor Qualification and Management Program

Plasma is collected in compliance with 21CFR 606 and 640, subpart G. Acceptable donors must pass requirements established for protein electrophoresis pattern, protein composition, hematocrit level, ALT (alanine aminotransferase) value and minimum total protein value. All approved donor units are tested and found negative (non-reactive) for Syphilis by FDA approved methods. Each source donor unit used is further tested and found negative for HBsAg (Hepatitis B Surface Antigen), HIV-1/2 (Human Immunodeficiency Virus Type 1 and 2), HIV-1Ag or HIV-1 NAT and HCV (Hepatitis C Virus) by FDA approved methods.

### Production and Packaging

Normal human serum is prepared from approved units of U.S. licensed source plasma. Plasma is collected through plasmapheresis using citrate as an anti-coagulant. Approved plasma units are then converted into serum by defibrinating the plasma. No preservative is added. Pre-screened serum is pooled, filtered by an in-line process that uses three 0.1µm filters, bottled and quality control tested before it is released for distribution.

### Storage and Handling

The human serum is supplied in gamma irradiated, sterile PETG or PETE bottles. We recommend that the serum be stored frozen at a temperature of -5°C to -20°C. Multiple freeze-thaw cycles of the serum should be avoided as this may lead to deterioration of the product. Always use aseptic techniques when handling the serum.

### Caution

Human serum products should always be considered potentially infectious and handled accordingly. Although all of the human donors are tested for and have been found negative for several virus antibodies and antigens, no known test method can offer complete assurance that products derived from human blood will not transmit infectious disease.

### Shipping

Serum is shipped frozen by next day air in insulated containers packed with dry ice.

*This product is manufactured for research and development purposes only. It is not intended for any human or animal diagnostic, therapeutic or other clinical uses. It is also not for agricultural, food, drug, cosmetic or household use. The use of these products must be supervised by a person technically qualified to handle potentially hazardous material.*