Human Thrombin: Information Sheet

For use in the manufacture of Human AB converted serum

The Human Thrombin used by Access Cell Culture LLC in the production of Human AB Converted serum, suitable for further manufacturing is a product manufactured for therapeutic use.

Human AB Converted serum using recombinant human thrombin are not currently available. This is due to the fact that recombinant human thrombin currently exists in insufficient volumes for use in manufacturing.

1. Identification and verification by barcodes to ensure full traceability

- All donations are cross-referenced with their certificates of analysis, previously recorded in the donor centre computer system.
- All test results, including viral marker tests, are verified on all donations once they are received from the donation centres.
- Visual and computerized checks are performed on all donations.
- Only inspected donations that are fully traceable are accepted.

2. ELISA and NAT testing

- Plasma donations are tested individually by Enzyme Linked Immunoabsorbent Assay (ELISA) for HBsAg, HIVAb and HCVAb.
- Each unit is screened in mini-pools of ≤ 512 units using Nucleic Acid Amplification Technique (NAT testing) for HIV-1 and HCV. Mini-pool NAT testing allows for specific identification and isolation of a single questionable donation for removal prior to production.

3. Inventory-hold and look-back - an additional safety measure

All plasma donations are stored for a minimum of 60 days before being used in production. This inventory-hold gives an opportunity to reject donations of any donor rejected because of a seroconversion in subsequent donations (look-back).

4. Final computer verification, the only way plasma is released

Each donation is computer checked again before it is sent for plasma derivatives production which guarantees that each donation has satisfied all controls.

5. ELISA and NAT testing in the fractionation pool prior to manufacturing

Once accepted for production, individual units of plasma are combined into a larger fractionation pool. Fractionation pools are then tested, once again using ELISA for HIVAb, HBsAg and HCVAb and NAT techniques for HIV-1 and HCV.

6. The manufacturing process includes several steps for maximum safety of the final product

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- Specific pathogen elimination steps are deliberately introduced into the manufacturing process as an additional safety measure (Solvent/Detergent and Nanofiltration).
- Non-specific pathogen elimination steps are purification steps which form part of the production process and have demonstrated capability to eliminate pathogens (e.g. Affinity Chromatography).

***Important Safety Information**: As with all plasma-derived products, the risk of transmission of infectious agents, including viruses, and theoretically, the Creutzfeldt-Jakob disease (CJD) agent, cannot be completely eliminated.*

Viral Inactivation of Thrombin

There are two steps of viral inactivation for the Thrombin; nanofiltration and Solvent/Detergent treatment. Both are employed in the manufacture of this product and are GMP processes.

Solvent/detergent S/D Treatment

The manufacturing steps comprise a comprehensive, multi-layered pathogen safety program to substantially reduce the risks and provide reasonable assurance that products are safe.

As a complementary safety measure to epidemiological surveillance and control of the plasma donor population, donor screening, and plasma testing, the manufacturing process incorporates robust steps in the manufacturing process with the validated capacity to inactivate and/or remove known and unknown pathogens.

This is a dedicated step with the capacity to inactivate lipid enveloped viruses such as HIV, HBV, and HCV by destroying the lipid coat and the associated virus binding sites.

This treatment ensures the effective inactivation of enveloped viruses while preserving the integrity and functionality of the therapeutic protein molecules. There has been no confirmed transmission of HIV, HBV, or HCV by S/D treated products since implementation in the mid-1980s.

Nanofiltration

There is a comprehensive, multi-layered pathogen safety program to substantially reduce the risks and provide reasonable assurance that products are safe.

As a complementary safety measure to epidemiological surveillance and control of the plasma donor population, donor screening, and plasma testing.

Viruses are made up of many proteins and are larger than the therapeutic protein molecules. Nanofilter pores allow the therapeutic protein molecules to pass through, but viruses are too large to pass through the pores and can be effectively retained within the nanofilter.

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