



**Fraction IV Paste** from Cohn Fraction IV cold ethanol plasma fractionation

**Product # PS510**

- Made from plasma of US origin collected from qualified human whole blood or source plasma donors at Blood Establishments with a current valid FDA Registration Certificate, collected according to FDA guidelines.
- Paste material manufactured according to documented procedures and GMP guidelines.
- Labeling: Each paste unit will be labeled with product description and batch lot number.
- Appearance: Yellow to brown in color, free of particulate matter.
  - The individual plastic bag contents homogeneous in color and consistency with no unusual odor other than ethanol.
- Included with each shipment:
  - Signed Certificate of Compliance with the following information:
    - Certification of testing:

Each donor unit used in the production of the paste has been tested by an FDA licensed laboratory with FDA licensed test kits.

Test results Negative or Non-Reactive for HBsAg, anti-HBc, anti-HIV 1/2, anti-HTLV I/II, anti-HCV, and Syphilis, HIV -1 RNA and HCV RNA. Results for other viral tests if performed such as HBV NAT, West Nile Virus and Chagas (T. cruzi) Negative or Non-Reactive.

In addition, the plasma may be tested by PCR for HAV, HBV, HCV, HIV and Parvo B-19.
    - Certification of Storage Temperature: The paste has been stored at -20 C or below.
  - Certificate of Analysis: Analysis of paste: Batch number, pH, total protein, albumin and globulin levels, weight of the paste batch supplied.
- Packaging: Plastic bags packed in boxes with insulation material and dry ice
- Shipping: Depends on customer specification.
  - Transported to storage facility or final destination by freezer truck.
  - Can be air-freighted in containers with dry ice.
  - Next Day Delivery by Federal Express with dry ice
- Order Lead Time: Depends on required quantity. Contracts and Standing Orders available.