

# Native Human Fibrinogen Reference Standard

**Cat. No.** Fibrinogen-21HRS    **Lot. No.** (See product label)

## SPECIFICATION

### Product Overview

|                  |                                                                                                                                                                                                                                                                                                                                                             |
|------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Species</b>   | Human                                                                                                                                                                                                                                                                                                                                                       |
| <b>Source</b>    | Human Plasma                                                                                                                                                                                                                                                                                                                                                |
| <b>Tag</b>       | Non                                                                                                                                                                                                                                                                                                                                                         |
| <b>Form</b>      | Freeze-dried powder                                                                                                                                                                                                                                                                                                                                         |
| <b>Stability</b> | Accelerated degradation studies have indicated that this material is suitably stable, when stored at -20°C or below, for the assigned values to remain valid until the material is withdrawn or replaced. These studies have also shown that the material is suitably stable for shipment at ambient temperature without any effect on the assigned values. |
| <b>Usage</b>     | This standard is primarily intended to be used to calibrate secondary and/or in-house working fibrinogen concentrate standards.                                                                                                                                                                                                                             |
| <b>Storage</b>   | Unopened ampoules should be stored at -20°C. After reconstitution, any unused material must be discarded, not frozen for later use.                                                                                                                                                                                                                         |
| <b>contents</b>  | The raw material was a plasma-derived fibrinogen concentrate, prepared using precipitation and chromatography methods. Manufacturing of this product also included 2 viral inactivation steps, solvent detergent treatment and heat treatment at                                                                                                            |

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80°C for 72 hours. After reconstitution, the concentrate material was pooled and formulated in the following buffer: 40mM Tri-Sodium Citrate.2H<sub>2</sub>O, 20mM Tris-HCl, 3% sucrose (w/v), 4mM L-arginine-HCl (pH 7.3). The formulated material was filled and freeze-dried in sealed glass ampoules, under conditions required for International Standards. One ml of this material was dispensed into each of approximately 10,000 ampoules.

**Shipping**

Because of the inherent stability of lyophilized material, may ship these materials at ambient temperature.

**UNITAGE**

The assigned potencies are:  
Clottable Protein - 10.9 mg/ampoule  
Total Protein - 15.0 mg/ampoule

**USE OF MATERIAL**

No attempt should be made to weigh out any portion of the freeze-dried material prior to reconstitution.  
The total contents of the ampoule should be reconstituted at room temperature with 1 ml distilled water, dissolved by gentle swirling to avoid froth and transferred immediately to a suitable plastic tube. The reconstituted Standard is stable for up to 3 hours at room temperature.

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