

**FOR INFORMATION USE ONLY**  
**Not to be used for performing the assay.**  
**Refer to the insert accompanying kit**  
 Catalogue #150708-OEM

**Minutex® D-dimer  
 Positive Control**  
 For *in vitro* diagnostic use



**I. INTENDED USE**

The Minutex® D-dimer Positive Control is intended to be used as a quality control for the Minutex® D-dimer (Biopool® cat# 150707) a semi-quantitative test.

**II. REAGENT**

**A. Reagent Description**

The Minutex® D-dimer Positive Control contains 0.2 ml of lyophilised human plasma enriched with fibrin D-dimer.

**B. Reagent Preparation**

Reconstitute each vial by adding 0.2 ml of Saline Solution (Biopool catalogue #150712). Agitate the solution at room temperature (19-25°C) until content is fully dissolved, about 5 minutes.

**III. ANALYSIS**

Agglutination pattern at 200 seconds	Specifications
Positive Control undiluted 1:1	Positive
Positive Control diluted 1:2	Positive
Positive Control diluted 1:4	Positive
Positive Control diluted 1:8	Negative

**IV. STORAGE AND STABILITY**

Store at 2-8 °C until expiry date.

Reconstituted, capped product is stable for 1 month when stored at 2-8 °C.

**V. WARNINGS AND PRECAUTIONS**

The Minutex® D-dimer Positive Control is of human origin. Each donor unit of source plasma used in these products has been tested and found negative for HBsAg, anti-HIV I+II, and anti-HCV by FDA-approved methods. However no test can offer complete assurance that products derived from human blood will not transmit infectious disease. As with all materials of human origin, this product should be handled as a potentially infectious agent.

All wastes containing biological material should be properly labelled and stored separately from other wastes. Dispose of all waste materials according to prescribed international, national and local regulations.

The test should be used in conjunction with clinical observations and results of other laboratory tests.

**VI. KEY GUIDE TO SYMBOLS**



Use by



Lot



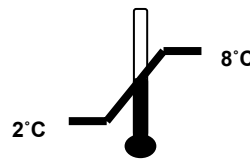
Catalogue number



Manufacturer



For *in vitro* diagnostic use



Store at 2-8°C



Consult accompanying documents



Biological risks

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