

# CERTIFICATE OF ANALYSIS

## HUMAN PLASMA PROTEIN

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### Human D-Dimer

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<b>Code No.</b>	<b>P202-3</b>
<b>Grade</b>	<b>Pure</b>
<b>Lot No.</b>	

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#### RECEIVER INFORMATION

**Expiry Date**

**Manufacture Date**

**Storage Temperature** Store below -15°C.

**Storage Notes** Avoid freeze thaw cycle.

**Shipping Notes** Dry Ice recommended.

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#### PRODUCT INFORMATION

**Source** Human plasma.

**Nominal Purity** Approximately 90% of the protein is D-Dimer.

**Presentation** Single homogenous batch, 0.2 µm filtered, supplied as a frozen solution in 0.05M NaH<sub>2</sub>PO<sub>4</sub> buffer, pH7.5, containing 0.15M NaCl and 0.09% NaN<sub>3</sub> with protease inhibitor cocktail.

**Recovery** In order to meet our customer needs, it should be noted that there is normally a dispensing overage allowance, and the product recovery may, therefore, be greater than expected. D-Dimer assays are not standardised therefore there will be variation with our D-dimer product when using different assays.

**Dilution** Recommended dilution of the D-dimer liquid material should be performed into a protein containing matrix i.e 1% HSA solution

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#### HEALTH AND SAFETY

**Application** For Research and Manufacturing Only.

#### Infectious Disease Tests

Starting material donor tested using FDA approved tests for:	Result
HIV 1 & 2 antibodies	
Hepatitis B Surface Antigen	
Hepatitis C virus antibodies	

**Precaution** No test can guarantee the absence of an infectious agent. Please handle as potentially hazardous.

**Material Safety**

For further information and technical details, please download a Safety Data Sheet at [www.bbisolutions.com](http://www.bbisolutions.com) or contact your BBI Account Manager.

**ANALYSIS**

TESTS	SPECIFICATIONS	RESULTS
<b><u>Determination Method</u></b>		
<b>D-Dimer content using Biomerieux VIDAS which measures in FEU.</b>	<b>&gt;1 mg/ml</b>	<b>mg/ml</b>
4-20% Polyacrylamide gradient gel Electrophoresis.	To show a band at approx. 200kDa corresponding to molecular weight of D-Dimer	Pass/Fail
Bioburden.	<100 CFU/ml	CFU/ml

**Physical Appearance** Clear colourless solution.

**Purity** Defined as a single band on coomassie stained gradient Polyacrylamide gel electrophoresis.

<b>Name:</b>		<b>Position:</b>	
<b>Signed:</b>		<b>Date:</b>	