

# CERTIFICATE OF ANALYSIS

## HUMAN TISSUE PROTEIN

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### Prostate Specific Antigen Alpha-1-Antichymotrypsin Complex

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<b>Code No.</b>	<b>P192-9</b>
<b>Grade.</b>	<b>Standard</b>
<b>Lot No.</b>	

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#### RECEIVER INFORMATION

**Expiry Date**  
**Manufacture Date**  
**Storage Temperature**      Below -15°C.  
  
**Storage Notes**                      Avoid freeze thaw cycles.  
**Shipping Notes**                      Dry ice recommended.

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#### PRODUCT INFORMATION

**Source**                                      Components from seminal fluid and human serum from healthy donors of American and European origin.

**Nominal Purity**                          ~70% of total protein is PSA- $\alpha_1$  ACT. Free PSA/Total PSA ratio <5%.

**Presentation**                              Single homogenous batch, 0.2 $\mu$ m filtered, supplied liquid frozen in 0.05M sodium phosphate buffer, pH 7.5, containing 0.15M NaCl and 0.09% NaN<sub>3</sub>.

**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.

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#### HEALTH AND SAFETY

**Application**                                  For Research and Manufacturing Only.

#### Infectious Disease Tests

Starting material pool tested using FDA approved test methods for:	Result
HIV 1 & 2 antibodies	
Hepatitis B Surface Antigen	
Hepatitis C virus antibodies	
Syphilis	
HIV / HBV / HCV By PCR and NAT	

**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>Total PSA assay by BBI RID. Total PSA component multiplied by 2.85 (to calculate PSA/ACT content)</b>	<b>&gt;1.0 mg/ml</b>	<b>mg/ml</b>
SDS-Polyacrylamide Gel Electrophoresis	To show a major band corresponding to PSA- $\alpha_1$ ACT complex with a molecular weight of approximately 81kD	Pass/Fail
Protein concentration estimated by optical density at 280nm	Report result	mg/ml
Free/ Total PSA ratio as determined by Roche Modular.	<5 %	%.
Bioburden	<100 cfu/ml	Pass/Fail

**Physical appearance** Clear colourless frozen liquid.

**Purity** Defined as the concentration of PSA-ACT calculated from the RID result for PSA as a percentage of total protein by OD 280nm.

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