

# CERTIFICATE OF ANALYSIS

## HUMAN SERUM PROTEIN

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### Human Immunoglobulin G (IgG)

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<b>Code No.</b>	<b>P142-1</b>
<b>Grade</b>	<b>Highly Pure</b>
<b>Lot No.</b>	

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#### RECEIVER INFORMATION

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**Expiry Date**

**Manufacture Date**

**Storage Temperature** Store at 2-8°C.

**Storage Notes** Do not freeze.

**Shipping Notes** Cool pack.

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#### PRODUCT INFORMATION

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**Source** Pooled normal human serum/plasma.

**Nominal Purity** >96%.

**Presentation** Single homogenous batch, 0.2µm filtered, supplied lyophilised from 0.02M NH<sub>4</sub>HCO<sub>3</sub> solution. May contain traces of buffer salts.

**Reconstitution Advice** Use of phosphate buffer, pH >7.0 containing 0.15M NaCl, is recommended. For maximum recovery of the product, we would strongly advise that reconstitution is performed directly into supplied vial.

**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

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**Application** For Research and Manufacturing Only.

#### Infectious Disease Tests

Starting material serum donor tested using FDA approved tests for:	Result
HIV I & II antibodies	
Hepatitis B surface antigen	
Hepatitis C 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>Protein concentration by optical density at 280nm using <math>E_{1cm}^{0.1\%} = 1.38</math></b>	<b>&gt;1 mg/ml</b>	<b>mg/ml</b>
Polyacrylamide Gel Electrophoresis	To show one diffuse band corresponding to IgG molecular weight	Pass/Fail
SDS-Polyacrylamide Gel Electrophoresis	To show one major band corresponding to IgG molecular weight	Pass/Fail
Radial Immunodiffusion (RID) assays vs. Behring standard	To show a positive reaction	Pass/Fail
IgA and IgM levels (Combined)	<2.0% of the total IgG content by RID	Pass/Fail
Bioburden	<100 CFU/ml	Pass/Fail

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**Physical Appearance**      White lyophilised solid.

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**Purity**                      Defined by coomassie stained SDS PAGE.

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