

# CERTIFICATE OF ANALYSIS

## HUMAN URINE PROTEIN

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### Human Chorionic Gonadotrophin (hCG)

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<b>Code No.</b>	<b>P111-0</b>
<b>Grade</b>	<b>Highly Pure</b>
<b>Lot No.</b>	

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#### RECEIVER INFORMATION

<b>Expiry Date</b>	
<b>Manufacturing Date</b>	
<b>Storage Temperature</b>	Store at 2-8°C.
<b>Storage Notes</b>	Do not freeze.
<b>Shipping Notes</b>	Cool pack.

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#### PRODUCT INFORMATION

<b>Source</b>	Protein extract of pregnancy urine.
<b>Nominal Purity</b>	≥96%
<b>Presentation</b>	Single homogenous batch, 0.2µm filtered, supplied lyophilised from 0.02M NH <sub>4</sub> HCO <sub>3</sub> . May contain traces of buffer salts.
<b>Additional Information</b>	Purity of pure hCG is >15,000 iu/mg.
<b>Reconstitution Advice</b>	Use of phosphate buffer, pH >7.0 containing 0.15M NaCl is recommended. To ensure full product recovery, it is advised that reconstitution is performed directly into supplied vial incorporating further washings with the reconstitution buffer.
<b>Recovery</b>	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

<b>Application</b>	For Research and Manufacturing Only.
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#### Infectious Disease Tests

Starting material tested for:	Result
HIV 1 & 2 antibodies	
Hepatitis B surface antigen	
Hepatitis C antibodies	

<b>Precaution</b>	No test can guarantee the absence of an infectious agent. Please handle as potentially hazardous.
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<b>Material Safety</b>	For further information and technical details, please download a Safety Data Sheet at <a href="http://www.bbisolutions.com">www.bbisolutions.com</a> or contact your BBI Account Manager.
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**ANALYSIS**

TESTS	SPECIFICATIONS	RESULTS
<b><u>Determination Method</u></b>		
Radial Immunodiffusion Assay Vs. 4 <sup>th</sup> International Reference Preparation for hCG Quantitation	1mg vial reconstituted with 1ml buffer to recover >14,000 iu/ml	iu/ml
SDS-Polyacrylamide Gel Electrophoresis	To show one band corresponding to unreduced glycosylated hCG	Pass/Fail
Bioburden	<100 CFU/ml	Pass/Fail

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**Physical Appearance**      White lyophilised powder.

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**Purity**                      Defined as a major band on Coomassie stained SDS-PAGE.

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