

CERTIFICATE OF ANALYSIS

HUMAN URINE PROTEIN

Human Chorionic Gonadotrophin (hCG)

Code No.	P111-6
Grade	Standard
Lot No.	

RECEIVER INFORMATION

Expiry Date
Manufacturing Date
Storage Temperature Store at 2-8°C.

Storage Notes Do not freeze.
Shipping Notes Cool pack.

PRODUCT INFORMATION

Source Protein extract of pregnancy urine.
Nominal Purity >65%, activity >9000 international units (iu) per mg of total protein.
Presentation Single homogenous batch, 0.2µm filtered, supplied lyophilised from 0.02M NH₄HCO₃. May contain traces of buffer salts.
Reconstitution Advice 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.
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.

HEALTH AND SAFETY

Application For Research and Manufacturing Only.

Infectious Disease Tests

Starting material tested using FDA approved tests for:	Name of test	Result
HIV 1 & 2 antibodies		
Hepatitis B surface antigen		
Hepatitis C antibodies		

Starting material tested using Polymerase Chain Reaction (PCR) for:	Result
HIV-1/HIV-2 PCR	
Hepatitis B virus PCR	
Hepatitis C virus PCR	

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 or contact your BBI Account Manager.

ANALYSIS

TESTS	SPECIFICATIONS	RESULTS
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Determination Method

Radial Immunodiffusion Assay vs. 4th International Reference Preparation for hCG Quantitation. Protein Concentration Determination by Dry Weight.	> 9000 iu/mg	iu/mg
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Contamination profile at hCG concentration 2500iu/mL

LH by Abbott Architect	<400 iu/L	iu/L
TSH by Abbott Architect	<2 mIU/mL	mIU/mL
FSH by Abbott Architect	<352 mIU/mL	mIU/mL
AFP by Abbott Architect	<26 ng/mL	ng/mL
Bioburden	< 100 CFU/ml	Pass/Fail

Physical Appearance	White lyophilised powder.
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Purity	Defined by potency as a proportion of pure hCG at 15,000 iu/mg.
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Name:		Position:	
Signed:		Date:	