

CERTIFICATE OF ANALYSIS

HUMAN CELL LINE PROTEIN

Human CA15-3

Code No.	P301-4
Grade	Low Cross Contamination
Lot No.	

RECEIVER INFORMATION

Expiry Date (5 years from manufacturing date)

Manufacturing Date

Storage Temperature Store below -15°C.

Storage Notes Avoid freeze thaw cycles.

Shipping Notes Dry Ice recommended.

PRODUCT INFORMATION

Source Human carcinoma cell line.

Presentation Single homogenous batch, 0.2µm filtered, supplied frozen in a 0.05M sodium phosphate buffer, pH 7.5 containing 0.15M NaCl and 0.09% NaN₃.

HEALTH AND SAFETY

Application For Research and Manufacturing Only.

Infectious Disease Tests

Starting material tested using FDA approved tests for:	Result
HIV 1 & 2 antibodies	
Hepatitis B Surface Antigen	
Hepatitis C virus antibodies	
HIV 1 / HBV / HCV NAT	
Syphilis (RPR)	

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
<u>Determination Method</u>		
CA15-3 concentration by Roche Modular	> 10 Ku/ml	Ku/ml
CA125 concentration as determined by Roche Modular	< 15% of CA15-3	%
CA19-9 concentration as determined by Roche Modular	< 15% of CA15-3	%
CA72-4 concentration as determined by Roche Modular	< 10% of CA15-3	%
CYFRA 21-1 concentration as determined by Roche Modular	Report Result	µg/ml
CEA concentration as determined by Roche Modular.	Report Result	µg/ml
Protein concentration as determined by Pierce BCA method	Report result	mg/ml
Bioburden	< 100 CFU/ml	Pass/Fail

Physical Appearance Clear to opalescent colourless frozen liquid.

Purity Total measured contaminants are < 40% of the total CA15-3 concentration.

Name:		Position:	
Signed:		Date:	