CERTIFICATE OF ANALYSIS

HUMAN CELL LINE PROTEIN

Human CA19-9

Code No.	**P291-4**
Grade	**Low Cross Contamination**
Lot No.	

RECEIVER INFORMATION

Expiry Date

Manufacture 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 phosphate buffer, pH 7.5 containing 1.0M NaCl, 5mM EDTA and 0.09% NaN_3.

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:	Result
HIV 1 & 2 antibodies	
Hepatitis B Surface Antigen	
Hepatitis C virus antibodies	
HIV 1 / HBV / HCV (NAT)	
Syphilis	

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
Determination Method		
CA19-9 concentration by Roche Modular	**> 100 Ku/ml**	**Ku/ml**
CA19-9 concentration by Beckman Access (Post QC result to be deleted)	Report result	Ku/ml
CA125 concentration by Roche Modular.	< 10% of CA19-9	%
CA15-3 concentration by Roche Modular.	< 10% of CA19-9	%
CA72-4 concentration by Roche Modular.	< 8% of CA19-9	%
CEA concentration by Roche Modular.	< 8%* of CA19-9	%
Protein concentration as determined by Pierce BCA method.	Report result	mg/ml
Bioburden.	< 100 CFU/ml	Pass/Fail

* % calculated using conversion 1Ku=1µg.

Physical appearance Clear colourless frozen liquid.

Purity Total measured contaminants are < 40% of the CA19-9 concentration.

Name:		**Position:**	
Signed:		**Date:**	