

CERTIFICATE OF ANALYSIS

HUMAN CELL LINE PROTEIN

Human CYFRA 21-1 (Cell Line)

Code No.	P246-4
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 cell line.

Presentation

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

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 for:	Result
HIV 1 & 2 antibodies	
Hepatitis B Surface Antigen	
Hepatitis C virus 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 or contact your BBI Account Manager.

ANALYSIS

TESTS	SPECIFICATIONS	RESULTS
<u>Determination Method</u>		
CYFRA 21-1 Concentration by Roche Modular.	> 25 µg/ml.	µg /ml.
CA125 Concentration by Roche Modular.	< 25% of CYFRA.*	%.
CA19-9 Concentration by Roche Modular.	< 1% of CYFRA.*	%.
CA15-3 Concentration by Roche Modular.	< 1% of CYFRA.*	%.
CA72-4 Concentration by Roche Modular.	< 1% of CYFRA.*	%.
NSE Concentration by Roche Cobas 6000.	< 1% of CYFRA.	%.
Coomassie Blue Stained 12% SDS-PAGE.	To show the presence of Albumin and Transferrin with no visible high molecular contaminants.	Pass/Fail.
Bioburden	< 100 CFU/ml.	Pass/Fail.
* Based on 1Ku ≡ 1µg		
Physical Appearance	Clear, pale yellow frozen solution.	

Name:		Position:	
Signed:		Date:	