

Certificate of Analysis



Ensuring Integrity in Every Cell Line

Product	NCI-H146	Passage Number	4
Species	Human	Cell Count per mL	3.33 million
Cytion™ Number	300182	Volume per ampule	1,5
Lot Number	300182-240425	Freeze Date	24.04.2025
Product Format	cryovial	Freeze Medium	Freeze medium containing FBS
Storage Conditions	Below -150°C	Expiration Date	Not applicable

At Cytion, we ensure the quality and reliability of our cell lines through in-house and third-party testing, including:

1. **STR Profiling:** To authenticate cell line¹ identity
2. **Virus Testing:** For species-specific² viruses where possible
3. **Mycoplasma Testing:** To prevent contamination.
4. **Interspecies Contamination Testing:** To ensure purity.
5. **Bacteria and Fungi Testing:** To ensure cells are free from microbial contaminants.

1: Human, Mouse, Rat, Hamster and Canine Species.

2: Human, Mouse, Rat, Hamster, Bovine, and Porcine Species.

Test Overview	Methodology	Acceptance Criteria	Outcome
Post-Freeze Viability	Viability assessment using Vi-CELL BLU by Beckman Coulter (analyzing 100 images per sample, 200 µl cell suspension per test)	≥70% post-thaw cell viability	70.9%
Recovery	Culture in the appropriate growth medium, microscopic evaluation	> 80% confluence within the expected recovery period	A T25 culture flask seeded at a density of 5.0×10^5 viable cells per mL typically reaches approximately 1.06×10^6 viable cells per mL within 2 days.
Growth Properties	Observation of cell culture behaviour to determine if cells are adherent, suspension, or semi-adherent	Cells exhibit expected growth properties consistent with the cell line's characteristics	Suspension
Sterility Testing	Visual inspection	Absence of microbial growth (bacterial, fungal, or yeast)	Pass
Mycoplasma Testing	PCR-based detection assay with specific primers targeting Mycoplasma DNA	No detectable Mycoplasma contamination confirmed by PCR	Pass

Interspecies Contamination Testing	Species	Status
	Mouse	-
	Rat	-
	Human	+
	Chinese hamster	-
	African green monkey	-

Authentication	Marker	Alleles
	AMEL	X
	CSF1PO	11
	D13S317	11, 12
	D16S539	11
	D18S51	15, 17
	D21S11	30
	D3S1358	11
	D5S818	12
	D7S820	9, 10
	D8S1179	12, 14
	FGA	23
	Penta_D	13
	Penta_E	12
	TH01	6, 9.3
	TPOX	8, 11
	vWA	14, 16
Identity match	100%	

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Species-Specific Pathogen Testing	Pathogen	Result
	Hepatitis A	-
	Hepatitis B	-
	Hepatitis C	-
	HIV1	-
	HIV2	-
	HTLV 1	-
	HTLV 2	-

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Third-Party Certified Quality Assurance

Since 2023, IDEXX has conducted STR profiling, species-specific pathogen testing, and species contamination analysis to ensure the authenticity, purity, and safety of our cell lines.

IDEXX BioAnalytics

The information provided is believed to be accurate, but both the information and product are offered without warranty for any applications beyond those specified. This certificate confirms that the material has been tested and is pure to the best of our knowledge.

This product is intended solely for laboratory research use and is not for use in humans, animals, or diagnostics. Proper Biosafety Level practices are required.

Cytion products may not be resold, modified for resale, or used commercially without prior written consent from Cytion.

Manufactured in Germany under our ISO 9001:2015 certified Quality Management System, ensuring high standards of quality and reliability.

Dr. R. Steubing

ID: AC403092-89FF-4279-9FDE-5B950957F3FF
Reason: Approved <r.steubing@cytion.com>
May 14, 2025 10:35 AM CEST

Qualified personnel have validated the test results of this Certificate of Analysis and attested with their signature that the tests were conducted as reflected in the results presented here.