Certificate of Analysis

Ensuring Integrity in Every Cell Line

Product	HEp-2	**Passage Number**	3
Species	Human	**Cell Count per mL**	2.0 million
Cytion™ Number	300397	**Volume per ampule**	1.5
Lot Number	300397-070225	**Freeze Date**	07.02.2025
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 line[1] identity
2. **Virus Testing:** For species-specific[2] 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	96.8%
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 6.3 x 10^4 viable cells per cm^2 typically reaches approximately 100% confluence within 1 day.
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	Adherent
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

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	Marker	Alleles
Authentication	AMEL	X
	CSF1PO	9, 10
	D13S317	12, 13.3
	D16S539	9, 10
	D18S51	16
	D21S11	27, 28
	D3S1358	15, 18
	D5S818	11, 12
	D7S820	8, 12
	D8S1179	12, 13
	FGA	18, 21
	Penta_D	8, 15
	Penta_E	7, 17
	TH01	7
	TPOX	8, 12
	vWA	16, 18
	Identity match	100.0%

	Pathogen	Result
Species-Specific Pathogen Testing	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: 20A94D52-164C-4341-B19A-BE6EBE2E56FC
Reason: Approved <r.steubing@cytion.com>
April 14, 2025 12:43 PM 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.

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