Certificate of Analysis

Ensuring Integrity in Every Cell Line

Product	HEL	**Passage Number**	4
Species	Human	**Cell Count per mL**	3.3 million
Cytion™ Number	305022	**Volume per ampule**	1.5
Lot Number	305022-240724	**Freeze Date**	24.07.2024
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	88.3%
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 5.1 x 10^6 viable cells per flask typically reaches approximately 1.6 x 10^7 viable cells per flask within 3 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

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	Marker	Alleles
Authentication	AMEL	X
	CSF1PO	10, 11
	D13S317	9, 11
	D16S539	11
	D18S51	12, 16
	D21S11	29, 30.2, 31.2
	D3S1358	15
	D5S818	11
	D7S820	7
	D8S1179	13, 15
	FGA	21, 22, 23
	Penta_D	11, 13
	Penta_E	13, 18
	TH01	7
	TPOX	11
	vWA	14, 17
	Identity match	90.3%

	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: 17DB6CC3-68EE-4906-9F8A-EF171B9D6A82
Reason: Approved <r.steubing@cytion.com>
April 14, 2025 11:53 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.

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