

# Certificate of Analysis

## Ensuring Integrity in Every Cell Line



<b>Product</b>	HROHep03	<b>Passage Number</b>	33
<b>Species</b>	Human	<b>Cell Count per mL</b>	3.0 million
<b>Cytion™ Number</b>	300197	<b>Volume per ampule</b>	1.5
<b>Lot Number</b>	300197-219	<b>Freeze Date</b>	22.03.2019
<b>Product Format</b>	cryovial	<b>Freeze Medium</b>	Freeze medium containing FBS
<b>Storage Conditions</b>	Below -150°C	<b>Expiration Date</b>	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<sup>1</sup> identity
2. **Virus Testing:** For species-specific<sup>2</sup> 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
<b>Post-Freeze Viability</b>	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	90.2%
<b>Recovery</b>	Culture in the appropriate growth medium, microscopic evaluation	> 80% confluence within the expected recovery period	A T25 culture flask seeded at a density of $9.0 \times 10^4$ viable cells per cm <sup>2</sup> typically reaches approximately 35% confluence within 5 days.
<b>Growth Properties</b>	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
<b>Sterility Testing</b>	Visual inspection	Absence of microbial growth (bacterial, fungal, or yeast)	Pass
<b>Mycoplasma Testing</b>	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	9, 11
	D13S317	11, 12
	D16S539	9, 12
	D18S51	12, 17
	D21S11	30
	D3S1358	15, 16
	D5S818	10, 12
	D7S820	8, 11
	D8S1179	13, 14
	FGA	19, 22
	Penta_D	9
	Penta_E	10, 11
	TH01	7, 9
	TPOX	8
	vWA	16, 17
	Identity match	100.0%



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*

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April 14, 2025 04:53 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.