Certificate of Analysis

Ensuring Integrity in Every Cell Line

Product	TMD8	**Passage Number**	3
Species	Human	**Cell Count per mL**	3.3 million
Cytion™ Number	305729	**Volume per ampule**	1.5
Lot Number	305729-150925	**Freeze Date**	15.09.2025
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	76.8%
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 8.2 x 10^5 viable cells per mL typically reaches approximately 2.6 x 10^6 viable cells per mL within 6 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	Direct inoculation on 8 media, 10-day incubation; microbial ID by MALDI-TOF MS ± anaerobic culture	No aerobic microbial growth (anaerobic if test was performed)	Sterility confirmed
Mycoplasma Testing	PCR-based detection assay with specific primers targeting Mycoplasma DNA	No detectable Mycoplasma contamination confirmed by PCR	Pass

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

	Marker	Alleles
Authentication	AMEL	X, Y
	CSF1PO	11, 12
	D13S317	9, 11
	D16S539	9, 11
	D18S51	13, 20
	D21S11	30
	D3S1358	17, 18
	D5S818	12, 13
	D7S820	8, 10
	D8S1179	10, 14
	FGA	17, 23
	Penta_D	9, 12
	Penta_E	5, 10
	TH01	6, 7
	TPOX	11
	vWA	14, 18
	Identity match	100.0%

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

	Pathogen	Result
Post-production sterility and mycoplasma testing	Bacterial growth	-
	Fungal growth	-
	Mycoplasma sp.	-

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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: 16B377EA-8644-44EE-92C9-5EE96877FCBF
Reason: Approved <r.steubing@cytion.com>
December 05, 2025 12:58 PM CET

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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