

Certificate of Analysis

Stem Cell Cryopreservation Solution, USP Grade (Chemical-Defined)

Cat No.: F109-20 / F109-100
Production Date: 21st November, 2024
Storage: 2-8 °C

Lot No.: F10924112101
Expiry Date: 20th November, 2027
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Physical and Chemical Analysis

	Specifications	Results
Appearance	Colorless clear liquid	Pass
pH ^[1]	7.0 ~ 9.0	7.52
Osmolality ^[2]	< 2500 mOsm/kg	2336 mOsm/kg
Endotoxin ^[3]	≤0.5 EU/ml	≤0.25 EU/ml

Sterility Testing

	Specifications	Results
Sterility ^[4]	Negative	Pass
Mycoplasma ^[5]	Negative	Pass

Cell Culture Test

	Specifications	Results
Recovery Rate	≥ 90%	99.6%

References

- [1] Potentiometric Determination; Current Edition EP
- [2] Freeze-Point Depression; Current Edition EP
- [3] Gel-clot technique; Current Edition EP
- [4] Direct Inoculation; Current Edition EP
- [5] Culture + Indicator Cell Assay

These signatures indicate the material mentioned above has met specifications and has been reviewed by the quality unit.

Quality Statement : This product is manufactured, tested and released in accordance with GMP guidelines.

This product complies with ISO 13485.

Signature: 
Position: Approver
Issue date: 5th December, 2024