



Certificate of Analysis

STEMPRO® Chondrogenesis Supplement

Catalog Number: A10064

Lot Number: 2060926

Storage Temperature: -5 to -20C

Storage Instructions: Store in the dark

Expiration Date: 2020-03

For research use only. Not for use in diagnostic procedures.

TEST	SPECIFICATION	RESULT	UNITS
Anti-HCV	Non Reactive	Non Reactive	
Anti-HIV 1	Non Reactive	Non Reactive	
Anti-HIV 2	Non Reactive	Non Reactive	
¹ Chondrogenesis Growth Assay	Acceptable	Acceptable	
² Endotoxin Testing, as (1X)	>=0 to <=50	<0.500	EU/mL
HBsAg	Non Reactive	Non Reactive	
³ PCR Analysis	Acceptable	Acceptable	
⁴ Sterility Testing	Negative	Negative	

Read SDS

CAUTION: Human origin materials are non-reactive (donor level) for Anti-HIV 1 and 2, Anti-HCV, and HBsAg. Handle in accordance with established bio-safety practices.

Quality Systems Department

Date: 10-Apr-2019

REFERENCES:

- 1 Each lot of supplement is evaluated for growth and differentiation. During the growth assay, Human Mesenchymal Stem cells (hMSCs) are recovered from cryopreservation and plated into a 75 cm² flask. The cells are subcultured, plated and further expanded in a 225 cm² flask. The cells are harvested from the flask, resuspended at a high density, and placed as micromass cultures on a 100 mm culture dish. An aliquot of the cell solution is treated with Trizol and frozen. The culture dish are fed with complete media (supplemented with the respective test supplements) and allowed to differentiate for seven days. The differentiated chondrogenic pellets are harvested, treated with collagenase type II, resolubilized in Trizol and frozen. The Trizol-treated undifferentiated and differentiated cells are then forwarded for PCR analysis. To be considered acceptable, the test samples must demonstrate acceptable growth performance and pellet formation, and require the presence of B2M, CD73 and SPP1 markers in PCR analysis.
- 2 Current United States Pharmacopeia, <85> Bacterial Endotoxins Test.
- 3 Thermo Fisher Scientific Specifications.
- 4 Current Edition of USP, Thermo Fisher Scientific Modified.

EXAMPLE