

CERTIFICATE OF ANALYSIS

Product	Physiologix™ XF Human Growth Factor Concentrate, Sterile
Part Number	320
Lot Number	0058-01-001
Volume	10 mL
Date of Manufacture	08 / 2021
Storage	≤ -70°C

GENERAL/STERILITY

TEST	SPECIFICATION	RESULTS	UNITS
Visual examination	Clear amber liquid	Pass	N/A
Endotoxin	≤ 0.25	< 0.20	EU/mL
Sterility	Sterile	Sterile	N/A
Mycoplasma	Not Detected	Not Detected	N/A
pH	6.0-8.0	7.1	N/A
Total Protein	As Reported	14.53	mg/mL

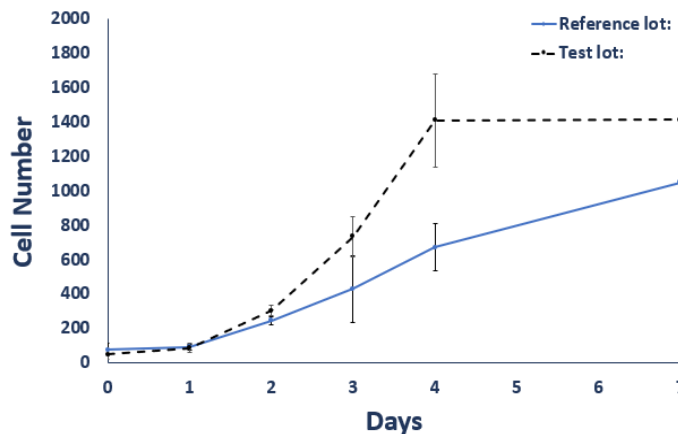
ADVENTITIOUS AGENTS SCREEN*

ADVENTITIOUS AGENT	SPECIFICATION	RESULTS
Antibody detection (unexpected antibodies to red cells)	Not Detected	Not Detected
Human Immunodeficiency Virus (HIV) 1 (M and O) & 2	Not Detected	Not Detected
Hepatitis B & C Viruses	Not Detected	Not Detected
Human T-Lymphotropic Virus Types I and II	Not Detected	Not Detected
Treponema pallidum (Syphilis)	Not Detected	Not Detected
Trypanosoma cruzi (Chagas)	Not Detected	Not Detected
West Nile Virus (WNV)	Not Detected	Not Detected
Zika Virus (ZIKV)	Not Detected	Not Detected

*Performed on raw material from donor.

FUNCTIONAL PROFILE

Figure 1. Proliferation curve of bone derived mesenchymal stem cells when grown in two lots of Physiologix™ XF hGFC for seven days.



M. Usher
Quality Systems Manager

Date