

Certificate of Analysis

Product	Physiologix™ XF Human Growth Factor Concentrate, Sterile
Part Number	322
Lot Number	0583-01-001
Volume	100 mL
Date of Manufacture	01JAN2024
Storage	≤ -70°C

GENERAL / STERILITY

TEST	SPECIFICATION	RESULTS	UNITS
Visual examination	Clear amber liquid	Pass	N/A
pH	6.0-8.0	6.78 @ 25°C	N/A
Total Protein	As Reported	20.56	mg/mL
Endotoxin	≤ 0.25	< 0.2500	EU/mL
Sterility	Sterile	No Growth	N/A
Mycoplasma	Not Detected	Not Detected	N/A

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

**Performed on raw material from donor.*

FUNCTIONAL PROFILE

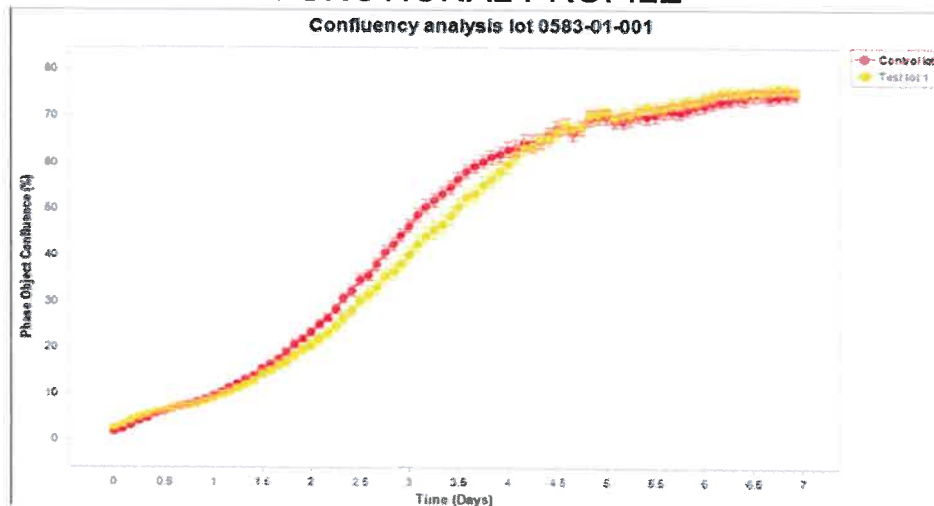


Figure 1. Proliferation curve of bone derived mesenchymal stem cells when grown in three lots of Physiologix™ XF hGFC for seven days.

A. Longest
Quality Assurance Manager

Date

09MAY2024