



CERTIFICATE OF ANALYSIS

Addendum

GemCell™ Plus Xeno-Free Human Serum AB

(Catalog Number 100-912-100, 100-912-005)

Lot Number: H424023

Date of Manufacture: Jul2024

Product Expiry: Jul2029

Origin: United States

Storage Temperature: ≤ -10°C

For Cell Culture, further Manufacturing or Research use only. Not for direct Therapeutic use.

Product Description: GemCell™ Plus Xeno-Free Human Serum AB is collected from healthy male donors of the AB serotype at FDA-licensed facilities located in the United States. Donor units are tested for infectious disease markers prior to processing and found to be non-reactive. GemCell™ Plus Xeno-Free Human Serum AB is converted to serum from human plasma using human thrombin and sterile-filtered through a 0.1 µm filter prior to freeze.

Test	Methodology	Specification	Analysis
Viral Testing	21 CFR 610.40		
Parvo B19 DNA NAT		Non-Reactive	Non-Reactive
HAV-NAT		Non-Reactive	Non-Reactive
HIV p24 Ag		Non-Reactive	Non-Reactive
Zika RNA NAT		Non-Reactive	Non-Reactive

All blood products are collected from stringently screened male donors at FDA-licensed collection centers located in the United States. Viral testing is performed on the individual donor units. All other testing is performed on the final product pool prior to release. Universal precautions should be used when handling this material. Precipitates may develop in this product upon freezing and/or thawing; this occurrence does not impact culture performance.

The testing that has been performed as part of this lot release has been reviewed by Quality Assurance personnel and has confirmed that the testing meets the specifications presented on this Certificate of Analysis.

Karen Zuniga

Name

QA Associate II

Title

27FEB2025

Date