

Certificate of Analysis

ExViGel-LUFO (Human Lung Fibrosis Origin)

FOR RESEARCH USE ONLY. Not intended for human or animal diagnostic or therapeutic uses. Human-derived products must be treated as potential pathogens. Users need to wear personal protective equipment during work.

Catalog number: LUFO

Batch numbers: 2.1.1

1. Information about donors

Batch number	Sex	Ethnicity	Age	Tissue origin	Pathology or Cause of death
LUN13-101	Male	Caucasian	45	Lung fibrosis	Fibrosis of lungs
LUN13-102	Male	Caucasian	67	Lung fibrosis	Fibrosis of lungs
LUN13-103	Female	Caucasian	73	Lung fibrosis	Fibrosis of lungs
LUN13-104	Male	Caucasian	39	Lung fibrosis	Fibrosis of lungs
LUN13-105	Male	Caucasian	47	Lung fibrosis	Fibrosis of lungs

Biological materials were collected from certified clinical hospitals. Clinical site provided ethical committee approval and conducted the collection in accordance with the Directive 2004/23/EC of the European Parliament

2. Viral RNA Detection by qPCR

Virus	Specification	Result
Hepatitis B		Positive <input type="radio"/> Negative X
Hepatitis C	Negative	Positive <input type="radio"/> Negative X
HIV-1 and HIV-2		Positive <input type="radio"/> Negative X

3. Product Information

Process	Human extracellular matrix was isolated and frozen by the patented method. No digestion or protein cleavage was applied.
Biosafety level	Human-sourced products should be handled at the Biological Safety Level 2 (BSL 2)
Production Date	01/10/2024
Last Control Date	11/10/2024
Packaging	5 mL suspension in a glass vial

4. Quality Control after Thawing

Criteria	Specification	Result	Conclusion	
Protein concentration	≥ 10mg/ml	16 mg/ml	Yes X	No <input type="radio"/>
Gelling	Gelation at +37 °C after 1h	Positive	Yes X	No <input type="radio"/>
Critical gelation concentration	≥ 5 mg/ml	8,7 mg/ml	Yes X	No <input type="radio"/>
GuaHCl concentration	< 1 x 10 ⁻³ M	< 1 x 10 ⁻³ M	Yes X	No <input type="radio"/>
Surfactants concentration	Non detected	Non detected	Yes X	No <input type="radio"/>
Microbial sterility	No microbial growth detectable	Undetectable	Yes X	No <input type="radio"/>

5. ELISA Measured Protein Concentration

Protein	Concentration
Elastin, mg/mg	0.213
Laminin, mg/mg	2.7665
Fibronectin, mg/mg	2.353
Tenascin, mg/mg	1.0
TGFA, ug/mg	0.44
EGF, ug/mg	0.00242
IGF1, ug/mg	0.00242
TGFB-1, ug/mg	24.13
Collagen Type-I, mg/mg	6.23
Collagen Type-II, mg/mg	0.452
Collagen Type-III, mg/mg	1,945
Collagen Type-IV, mg/mg	0.574
Collagen Type-V, mg/mg	0.312
Collagen Type-VI, mg/mg	0.167

6. AFM-based Measurements

Measurement	Result
AFM-based colloid size at sol state (nm)	20.34
AFM-based collagen fibre formation (Yes/No)	Yes
AFM-based collagen fiber diameter (nm)	61.4
Elasticity Modulus at Maximum Concentration (kPa)	0,813
Elasticity Modulus at Maximum Gelation Dilution (kPa)	0,59

7. Biocompatibility

Experiment	Results
Primary Human Hepatocytes (reference plateable batch) confluency	30%
HepG2 doubling time	38 hours
Weight loss in BALB/c mouse (relative to Matrigel), 14 days exposure	TBD

8. Visa for Batch Release

Name	Signature	Date
Vladyslav Moseiko		11/10/2024