

Certificate of Analysis

ExViGel-LHO (Human Lung 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: HLO

Batch numbers: HLO 1.2.1

1. Information about donors

Batch number	Sex	Ethnicity	Age	Tissue origin	Pathology or Cause of death
LUN13-108	Male	Caucasian	52	Lung	Hemorrhagic stroke
LUN13-109	Female	Caucasian	67	Lung	Hemorrhagic stroke
LUN02-125	Female	Caucasian	74	Lung	Lung cancer

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	08/09/2024
Last Control Date	17/09/2024
Packaging	5 mL suspension in a glass vial

4. Quality Control after Thawing

Criteria	Specification	Result	Conclusion	
Protein concentration	≥ 10mg/ml	13 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	7,3 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/g	0,498
Laminin, mg/g	1,143
Fibronectin, mg/g	1,132
Tenascin, mg/g	<8*10 ⁻⁵
TGFA, ug/g	0,00045
EGF, ug/g	0,00078
IGF1, ug/g	0,00095
TGFB-1, ug/g	0,0056
Collagen Type-I, mg/g	5,371
Collagen Type-II, mg/g	1,124
Collagen Type-III, mg/g	1,671
Collagen Type-IV, mg/g	1,082
Collagen Type-V, mg/g	0,513
Collagen Type-VI, mg/g	0,298

6. AFM-based Measurements

Measurement	Result
AFM-based colloid size at sol state (nm)	22,8
AFM-based collagen fibre formation (Yes/No)	Yes
AFM-based collagen fiber diameter (nm)	60,75
Elasticity Modulus at Maximum Concentration (kPa)	0,821
Elasticity Modulus at Maximum Gelation Dilution (kPa)	0,634

7. Biocompatibility

Experiment	Results
Primary Human Hepatocytes (reference plateable batch) confluency	33%
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		17/09/2024