

Certificate of Analysis

ExViGel-HLIO (Human Liver 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: HLIO

Batch numbers: 1.3.1

1. Information about donors

Batch number	Sex	Ethnicity	Age	Tissue origin	Pathology or Cause of death
LIN02-164	Male	Caucasian	67	Liver	Colorectal cancer
LIN09-148	Female	Caucasian	54	Liver	Colorectal cancer
LIN02-166	Female	Caucasian	44	Liver	Colorectal cancer
LIN05-110	Male	Caucasian	75	Liver	Colorectal cancer
LIN02-167	Male	Caucasian	41	Liver	Colorectal 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	14/10/2024
Last Control Date	22/10/2024
Packaging	5 mL suspension in a glass vial

4. Quality Control after Thawing

Criteria	Specification	Result	Conclusion	
Protein concentration	≥ 10mg/ml	12,4mg/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	7,4 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	0,854
Laminin, mg/g	0,731
Fibronectin, mg/g	0,821
Tenascin, mg/g	0,512
TGFA, ug/g	0,13
EGF, ug/g	<3,91*10 ⁻⁶
IGF1, ug/g	0,73
TGFB-1, ug/g	0,05
Collagen Type-I, mg/g	4,878
Collagen Type-II, mg/g	0,00031
Collagen Type-III, mg/g	3,05
Collagen Type-IV, mg/g	0,732
Collagen Type-V, mg/g	0,305
Collagen Type-VI, mg/g	0,489

6. AFM-based Measurements

Measurement	Result
AFM-based colloid size at sol state (nm)	22,6
AFM-based collagen fibre formation (Yes/No)	Yes
AFM-based collagen fiber diameter (nm)	62
Elasticity Modulus at Maximum Concentration (kPa)	0,81
Elasticity Modulus at Maximum Gelation Dilution (kPa)	0,62

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		22/10/2024