

# Certificate of Analysis

## ExViGel-STSO (Soft Tissue Sarcoma 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: STSO

Batch numbers: STSO 2.2.1

### 1. Information about donors

Batch number	Sex	Ethnicity	Age	Tissue origin	Pathology or Cause of death
STS02-137	Male	Caucasian	21	Soft tissue	Soft tissue sarcoma
STS02-138	Male	Caucasian	41	Soft tissue	Soft tissue sarcoma
STS02-139	Female	Caucasian	64	Soft tissue	Soft tissue sarcoma
STS02-140	Male	Caucasian	36	Soft tissue	Soft tissue sarcoma

*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 <input checked="" type="radio"/>
Hepatitis C	Negative	Positive <input type="radio"/> Negative <input checked="" type="radio"/>
HIV-1 and HIV-2		Positive <input type="radio"/> Negative <input checked="" type="radio"/>

### 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	15/07/2024
Last Control Date	24/07/2024
Packaging	5 mL suspension in a glass vial

#### 4. Quality Control after Thawing

Criteria	Specification	Result	Conclusion	
Protein concentration	≥ 10mg/ml	14.3 mg/ml	Yes <b>X</b>	No <input type="radio"/>
Gelling	Gelation at +37 °C after 1h	Positive	Yes <b>X</b>	No <input type="radio"/>
Critical gelation concentration	≥ 5 mg/ml	8.2 mg/ml	Yes <b>X</b>	No <input type="radio"/>
GuaHCl concentration	< 1 x 10 <sup>-3</sup> M	< 1 x 10 <sup>-3</sup> M	Yes <b>X</b>	No <input type="radio"/>
Surfactants concentration	Non detected	Non detected	Yes <b>X</b>	No <input type="radio"/>
Microbial sterility	No microbial growth detectable	Undetectable	Yes <b>X</b>	No <input type="radio"/>

#### 5. ELISA Measured Protein Concentration

Protein	Concentration
Elastin, mg/g	3,185
Laminin, mg/g	0,78
Fibronectin, mg/g	3,115
Tenascin, mg/g	0,004
TGFA, ug/g	1,556
EGF, ug/g	<3,91*10 <sup>-3</sup>
IGF1, ug/g	<6,25*10 <sup>-2</sup>
TGFB-1, ug/g	41
Collagen Type-I, mg/g	6,116
Collagen Type-II, mg/g	0,021
Collagen Type-III, mg/g	0,767
Collagen Type-IV, mg/g	0,000027
Collagen Type-V, mg/g	0,0041
Collagen Type-VI, mg/g	0,215

#### 6. AFM-based Measurements

Measurement	Result
AFM-based colloid size at sol state (nm)	21
AFM-based collagen fibre formation (Yes/No)	Yes
AFM-based collagen fiber diameter (nm)	61
Elasticity Modulus at Maximum Concentration (kPa)	0,852
Elasticity Modulus at Maximum Gelation Dilution (kPa)	0,652

## 7. Biocompatibility

Experiment	Results
Primary Human Hepatocytes (reference plateable batch) confluency	35
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		24/07/2024