

**SAMPLE****CERTIFICATE OF ANALYSIS**

HUMAN CRYOPRESERVED HEPATOCYTES

Spheroid, for in vitro analysis

Catalog number: HH3

SPHEROID

Batch number: HH3-187719

FOR RESEARCH USE ONLY. CAUTION: Not intended for human or animal diagnostic or therapeutic uses. Users should treat all human and animal cells as potential pathogens. Wear protective clothing and eyewear. Practice appropriate disposal techniques for potentially pathogenic or bio-hazardous materials.

1. Biological Material

Subject	Human
Age	70
Sex	Male
Ethnicity	Caucasian
Pathology	Colorectal Cancer, liver metastasis, 4 cycles of CT
Diabetes	No
Heart disease	Yes
High blood pressure	Yes
Smoking	No
Alcoholism	No
Medication	Flenox 0,4
Virological status	Negative for HBV, HCV, HIV

2. Product

Process	Hepatocytes were isolated and frozen by standard methods
Cell quality control date	26/07/2023
Packaging	0.5 mL vial with a minimum of 5×10^6 viable cells

3. Cell Quality Control

Criteria	Specification with one-step thawing protocol	Result	PASS/FAIL
Post-thaw viability	$\geq 80 \%$	82%	PASS
Number of viable cells per vial	$\geq 5 \times 10^6$	(5.6×10^6)	PASS
Number of days to form spheroids	7-14 days	10	PASS
Microbial sterility (under standard use conditions)	No microbial growth detectable	(Undetectable)	PASS

4. Cell Storage

Delivery and storage	Liquid nitrogen
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Product Certification

Name	Signature	Date
Tetiana Papurina		27.07.2023

Material is intended for the research purpose only, not for diagnostic or therapeutic use. Biological materials were collected from the certified clinical hospitals from the liver tumor resection. Clinical site provided ethical committee approval and conducted the collection in accordance to the Directive 2004/23/EC of the European Parliament, and following the regulations of the local Ministry of Health
