## **Certificate of Analysis**

Item number:

OES-ISO48-CXP1

Lot number:

CXP1-091

Line ID:

**ISO48** 

Donor Age/Sex:

43/Male

**Species:** 

Human

Tissue:

Colorectal Cancer

Volume per vial:

≥0.5mL

Date frozen:

04 Jul 2024

Format:

Organoids stored in freezing medium

Storage conditions:

Store at -150°C

Usage:

For research use only – organoids are single use only and not to be passaged for

DEVICES

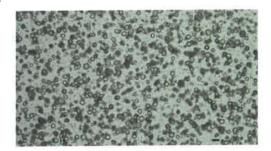
CofA Issue: 1

repeated use or for other organoid expansion processes

Characteristic	Specification	Result	
Passage number	Not applicable	P35	
Average organoids per vial	≥100,000	163,713	
Average organoid size post thaw	Report results	42.42 μm	
Growth after recovery	Growth observed over 7 days	Growth observed over 7 days	
(Visual observation)			
Mycoplasma			
(PCR based assay)	Not detected	Not detected	
Viral screening			
HIV-1, HIV-2	Not detected	Not detected	
HBV	Not detected	Not detected	
CMV	Not detected	Not detected	
EBV	Not detected	Not detected	
HPV	Not detected	Not detected	
(PCR based assay)			
Sterility			
Bacteria, yeast and fungi	Not detected	Not detected	
(Direct inoculation)			

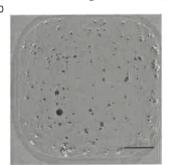
Representative image of organoids in culture:

4x magnification scale bar = 100μm

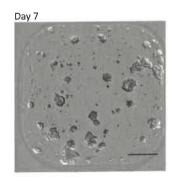


Representative images following thaw (4x magnification, scale bar = 700μm)

Day 0



Day 2



Manufacturing Facility: Molecular Devices (UK) Ltd | 1 Longwood Drive | Cardiff | CF14 7HY | United Kingdom Head Office: Molecular Devices (UK) Ltd | 660 – 665 Eskdale Rd | Winnersh Triangle | Wokingham | RG41 5TS | United Kingdom

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Item number:

OES-ISO48-CXP1

Lot number: Line ID: CXP1-091 ISO48 DEVICES

CofA Issue: 1

Written by:			
Name	Role	Signature	Date
William Newell	Senior Bioprocess Engineer	weull	15AUG-2024

QA approval:					
Name	Role	Signature	Date		
Ben Jones	QA Specialist	CBlones	15 Aug 2024		