

## BATCH CERTIFICATE

For Research Use Only

### PRODUCT INFORMATION AND QUALITY CONTROL

NAME OF PRODUCT	cfDNA in Plasma for Metagenomics		
DESCRIPTION	cfDNA in Plasma for Metagenomics is spiked with three different pathogen sequences in plasma; human proteins, electrolytes, EDTA, cfDNA / ctDNA in common plasma concentrations.		
CATALOG NUMBER	SID-000152		
<b>BATCH NUMBER</b>	<b>00836</b>		
MANUFACTURING CONDITIONS	<ul style="list-style-type: none"> <li>· Manufactured and sealed in class 2 safety cabinet</li> <li>· Manufactured according to DIN EN ISO 13485:2016</li> </ul>		
PACKAGE SIZE AND TYPE	<ul style="list-style-type: none"> <li>· 2D barcoded tube with screw cap</li> <li>· Material: Polypropylen (PP)</li> </ul>		
DATE OF MANUFACTURE	02.12.2024		
EXPIRY DATE	01.12.2026		
TARGET CONCENTRATION	20 ng/ml (dsDNA)		
TARGET QUANTITY	22 ng (dsDNA)		
NOMINAL VOLUME	1.1 ml		
PATHOGENS AND COPY NUMBER / PRODUCT	Candida orthopsilosis: 36149.30 copies/product		
	Legionella sainthelensis: 189822.51 copies/product		
	Varizella zoster virus: 88115.56 copies/product		
QUALITY	The copy number values are metrologically traceable to the natural units count 1 and ratio 1 and International System of Units (SI) derived units of volume.		
STORAGE CONDITIONS	+ 2-8 °C		
MANUFACTURING SITE	SensID GmbH Schillingallee 68, 18057 Rostock, Germany		
TEST METHOD AND ACCEPTANCE CRITERIA	Quality control	Test method	Acceptance criteria
	Fragmentation	Fragment length analysis: Agilent D5000 ScreenTape System <sup>1</sup> (Agilent Technologies)	Peak size 167 bp ± 15 % (142 bp – 192 bp)
	Quantification	dsDNA measurement: Qubit™ <sup>1</sup> 1X dsDNA HS Assay-Kit (Invitrogen)	dsDNA: 20 ng/ml ± 10 % (18 – 22 ng/ml)
	Copy number	Copy number analysis: ddPCR <sup>1</sup> (BioRad QX200™) calculated to copies/product	Candida orthopsilosis: 36149.30 ± 20 % (28919 – 43379) Legionella sainthelensis: 189822.51 ± 20 % (151858 – 227787) Varizella zoster virus: 88115.56 ± 20 % (70492 – 105739)
<sup>1</sup> measured from the original cfDNA			

RESULTS OF ANALYSIS	Quality control	Result		PASS / FAIL
	Fragmentation	172 bp		PASS
	Quantification	20.1 ng/ml (dsDNA)		PASS
	Copy number	Pathogen	CN/product	PASS / FAIL
		C. orthopsilosis	40,036	PASS
		L. sainthelensis	199,038	PASS
V. zoster virus		83,907	PASS	
<i>The table above indicates the values of the QC assays performed by SensID GmbH with a DNA input of 1 ng. The value for the respective mutation results from the mean value of QC samples according to ISO 2859-1:2014-08 (CN values are rounded). CN concentration values per product are based on droplet digital PCR (ddPCR) assay counts dilution factors, and droplet volume measurements. The detection of the amount of CNs may vary depending on the assay used. Therefore, due to assay properties, there may be deviations in the observed number of copies and allele frequencies compared to the values given here.</i>				
COMMENTS / REMARKS	not applicable			

Name and position/title of person authorising the batch release:

Björn Nowack, Managing Director

Date of batch release: 06.12.2024

Signature batch release: Björn Nowack

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