

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		
BATCH NUMBER	00577		
MANUFACTURING CONDITIONS	<ul style="list-style-type: none"> · Manufactured and sealed in class 2 safety cabinet · Manufactured according to DIN EN ISO 13485:2016 		
PACKAGE SIZE AND TYPE	<ul style="list-style-type: none"> · 2D barcoded tube with screw cap · Material: Polypropylen (PP) 		
DATE OF MANUFACTURE	18.09.2023		
EXPIRY DATE	17.09.2025		
TARGET CONCENTRATION	80 ng/ml (dsDNA)		
TARGET QUANTITY	88 ng (dsDNA)		
NOMINAL VOLUME	1.1 ml		
PATHOGENS AND COPY NUMBER / PRODUCT	Candida orthopsilosis: 149419.45 copies/product		
	Legionella sainthelensis: 950446.82 copies/product		
	Varizella zoster virus: 513479.15 copies/product		
QUALITY	<p>DNA quantity metrologically traceable to internationally certified reference material (ERM_AD442K lamdaDNA).</p> <p>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.</p>		
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 ¹ (Agilent Technologies)	Peak size 167 bp ± 15% (142 bp – 192 bp)
	Quantification	dsDNA measurement: Qubit ¹ dsDNA BR Assay Kit (Invitrogen)	dsDNA: > 80 ng/ml
	Copy number	Copy number analysis: ddPCR ¹ (BioRad QX200™) calculated to copies/product	<p>Candida orthopsilosis: 149419.45 ± 20% (119536 – 179303)</p> <p>Legionella sainthelensis: 950446.82 ± 20% (760357 – 1140536)</p> <p>Varizella zoster virus: 513479.15 ± 20% (410783 – 616175)</p>
¹ measured from the original cfDNA			

RESULTS OF ANALYSIS	Quality control	Result		PASS / FAIL
	Fragmentation	173 bp		PASS
	Quantification	89.6 ng/ml (dsDNA)		PASS
	Copy number	Pathogen	CN/product	PASS / FAIL
		C. orthopsilosis	149454	PASS
		L. sainthelensis	923294	PASS
	V. zoster virus	447874	PASS	
<p><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></p>				
COMMENTS / REMARKS	not applicable			

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

Björn Nowack, Managing Director

Date of batch release: 21.09.2023

Signature batch release: Björn Nowack

This document has been created electronically and is valid without signature.