

Batch Certificate

For Research Use Only

PRODUCT INFORMATION AND QUALITY CONTROL

NAME OF PRODUCT	SID-Plasma 1x (human) + cfDNA (wt)		
DESCRIPTION	Human proteins in common plasma concentrations, electrolytes, EDTA, cfDNA / ctDNA in common plasma concentrations		
CATALOG NUMBER	SID-0002		
BATCH NUMBER	SID-XXXX		
MANUFACTURING CONDITIONS	<ul style="list-style-type: none"> • Manufactured and sealed in class 2 safety cabinet • Bottled with qualified epMotion® 5075I and OPUS® Dispenser • At room temperature 		
PACKAGE SIZE AND TYPE	<ul style="list-style-type: none"> • 2D barcoded tube with screw cap • Material: Polypropylen (PP) 		
DATE OF MANUFACTURE	01 Oct 2018		
EXPIRY DATE	01 Oct 2019		
CONCENTRATION	80 ng/ml		
QUANTITY	400 ng		
NOMINAL VOLUME	5 ml		
QUALITY	sterile		
STORAGE CONDITIONS	+ 2-8 °C		
MANUFACTURING AND QUALITY CONTROL SITES	SensID GmbH Schillingallee 68, 18057 Rostock, Germany		
TEST METHOD AND ACCEPTANCE CRITERIA	Quality Control	Test Method	Acceptance criteria
	Fragmentation	Fragment Length Analysis Agilent High Sensitivity DNA Kit (Agilent Techn.)	peak size 167 bp ± 10% (151 bp – 181 bp)
	Quantification	Spectrophotometry ¹ ssDNA [ng/μl] = (A260- A320)*38 ²	18,5 – 21,5 ng/μl
	¹ cfDNA conc. measured before spiked in Plasma, because of LOD ² Protocol NK603 – Community Reference Laboratory for GM Food and Feed		

RESULTS OF ANALYSIS		Result	PASS/FAIL
	Fragmentation	167,0 bp	PASS
Quantification	20 ng/ μ l	PASS	

COMMENTS/REMARKS	Additional information that may be relevant to the importer and / or inspector. Compliance of the batch certificate (e.g. specific storage or transport conditions).
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Name and position/title of Person authorising the batch release:

Mr. Björn Nowack

Date of batch release: 02 Oct. 2018

Signature batch release: Björn Nowack