

CERTIFICATE OF ANALYSIS

Product name:	suPARnostic® AUTO Flex ELISA
Product code:	E001
Lot no.:	2205-EI-1
Expiry date:	2023-05
Country of origin:	Denmark
Storage conditions:	2-8 °C
Intended use:	For in vitro diagnostic use. For professional use only. suPARnostic standards are intended for establishing a standard curve for the quantitative immunological determination of human suPAR (soluble urokinase plasminogen activator receptor) by ELISA.
Standards a-e, CC:	Recombinant suPAR in PBS buffer with proprietary additives and 0,05% Bronidox as a preservative. The standards and curve control (CC) are intended to be used in combination with the reagents provided with suPARnostic® AUTO Flex ELISA code E001.

For the Instruction For Use, visit www.virogates.com/support

The undersigned hereby certifies the following data to be obtained by QC- and In-process tests.

Tests	Method	Date of test	Acceptance Criteria	Actual Result (ng/mL)	Expected variation (ng/mL)	Accepted/Rejected
suPAR Conc. Of STD A	ELISA	2022.05.19	suPAR conc. decreasing from STD A – STD E; values cannot overlap STD A and E within the expected ranges	14,0	N/A	ACCEPTED
suPAR Conc. of STD B				10,5		
suPAR Conc. of STD C				7,0		
suPAR Conc. of STD D				3,5		
suPAR Conc. of STD E				1,3		
suPAR Conc. Of CURVE CONTROL			Within the expected range	2,4	1,8 – 3,1	ACCEPTED
Standards R-squared (R ²)			R ² ≥0,995	0,998	N/A	ACCEPTED

Location of tests performance:

NUTOPI Sp. z o. o.
 Rubież 46H
 61-612 Poznań
 Poland

PRECAUTIONS AND RECOMMENDATIONS

Do not use components beyond indicated expiration date. Do not mix reagents from different kits.

Calculation of suPAR values from Raw OD's: Use the Calculation tool software available on www.virogates.com or contact info@virogates.com.

Quality Control (date/sign):


Tomasz Pielak (Jun 2, 2022 12:02 GMT+2)

Jun 2, 2022

Quality Assurance (date/sign):



Jun 2, 2022











Appendix 1 P 08-01 R011 CoA - ELISA Auto Flex 2205-E1-1

Final Audit Report

2022-06-02

Created:	2022-06-01
By:	Mia Søgaaard (mss@virogates.com)
Status:	Signed
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"Appendix 1 P 08-01 R011 CoA - ELISA Auto Flex 2205-E1-1" History

-  Document created by Mia Søgaaard (mss@virogates.com)
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