

## Certificate of Analysis

**Product name:** suPARnostic® AUTO Flex ELISA  
**Product code:** E001  
**Lot No.:** 2010-E1-1  
**Date of release:** 24.11.2020  
**Expiry date:** 2021-10  
**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 standard curve for the quantitative immunological determination of human suPAR (soluble urokinase plasminogen activator receptor) by ELISA.

**Standards a-e, CC:** Recombinant suPAR (soluble urokinase plasminogen activator receptor) in PBS buffer with proprietary additives and 0,05% Bronidox as 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](http://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 <b>STD A</b>	ELISA	23.11.2020	suPAR conc. decreasing from STD A – STD E; values cannot overlap  STD A and E within the expected ranges	13,6	N/A	Accepted
suPAR Conc. of <b>STD B</b>				10,2		
suPAR Conc. of <b>STD C</b>				6,8		
suPAR Conc. of <b>STD D</b>				3,4		
suPAR Conc. of <b>STD E</b>				1,3		
suPAR Conc. of <b>CURVE CONTROL</b>			Within the expected range	2,4	1,8 – 3,0	Accepted
Standards R-squared (R <sup>2</sup> )			R <sup>2</sup> ≥0,995	≥0,995	N/A	Accepted

**Location of tests performance:**

NUTOPI Sp. z o. o.  
 Rubież 46H / 248  
 61-612 Poznań  
 Poland

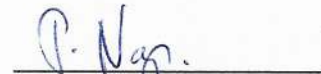
**PRECAUTIONS AND RECOMMENDATIONS**

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](http://www.virogates.com) or contact [info@virogates.com](mailto:info@virogates.com)

Date of approval: 24.11.2020

  
 Quality Control

  
 Quality Assurance


**suPARnostic®** – The **Risk** status marker

**Banevænget 13, 3460 Birkerød, Denmark**

Phone +45 21131336, Skype: virogates, E-mail: [info@virogates.com](mailto:info@virogates.com), Web: [www.virogates.com](http://www.virogates.com)