

Certificate of Analysis

Product name: suPARnostic® AUTO Flex ELISA
Product code: E001
Lot No.: 2006-E1-1
Date of release: 10.09.2020
Expiry date: 2021-06
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

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 | 23-26.06.2020 | suPAR conc. decreasing from STD A – STD E; values cannot overlap | 12,3 | N/A | Accepted |
| suPAR Conc. of STD B | | | | 9,2 | | |
| suPAR Conc. of STD C | | | | 6,1 | | |
| suPAR Conc. of STD D | | | | 3,1 | | |
| suPAR Conc. of STD E | | | | 1,2 | | |
| suPAR Conc. of CURVE CONTROL | | | Within the expected range | 2,1 | 1,6 – 2,7 | Accepted |
| Standards R-squared (R ²) | | | R ² ≥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 or contact info@virogates.com

Date of approval: 10.09.2020



 Quality Control



 Quality Assurance



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