

A Company of Sysmex Group



HYPHEN BioMed 155 rue d'Eragny 95000 Neuville-sur-Oise France

CERTIFICATE OF ANALYSIS

Product Description: ZYMUTEST CRP

Product Code: RK010A

Lot No.: FB0133

Expiration date: 2024-07-03

Components	Quantity	Lot	Expiration Date
Anti-(h) CRP F(ab') pre-coated plate	12x8 wells	FB0411	2025-08-11
CRP standard	3 vials	FB0322	2025-07-31
Control I	1 vial	FB0323	2025-07-31
Control II	1 vial	FB0324	2025-07-31
Anti-(h)- CRP HRP immunoconjugate	3 vials	FB0410	2025-08-14
Sample diluent	2x50 ml	FA1738	2025-03-10
Wash solution	1x50 ml	FA0257	2024-07-03
Conjugate diluent	1x25 ml	FA1119	2024-11-18
ТМВ	1x25 ml	210302D01	2025-03-30
Sulfuric Acid 0,45M	1x6 ml	FA0937	2024-10-14

Analytical Data	Specification	Result
Reactivity	A450 for 85 ng/ml ≥ 1.10	1.47
Calibration Curve and Accuracy	Controls Measured Values within acceptance ranges	PASS
Blank	< 0.100	0.02
Detection threshold	≤ 2.5 ng/mL	< 1 ng/mL

This is to certify that above product has been produced and passed the inspection according to specifications of HYPHEN BioMed.

Date of Approval: 2022-03-21

Quality Control Manager: S. LECOURT