



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

CERTIFICATE OF ANALYSIS

Product Description : ZYMUTEST Protein C

Product Code : RK027A

Lot No. : F1901187

Expiration date : 2022-04-02

Components	Quantity	Lot	Expiration Date
Anti (h) Protein C pre-coated plate	12x8 wells	F1903026	2022-04-08
Protein C Standard	3 vials	F1903013	2022-04-02
Protein C Control I	1 vial	F1903014	2022-04-02
Protein C Control II	1 vial	F1903015	2022-04-02
Anti-(h)-Protein C HRP immunoconjugate	3 vials	F1903029	2022-04-11
Sample diluent	2x50 ml	F1901067	2023-02-21
Wash solution	1x50 ml	F1900767	2022-12-06
Conjugate diluent	1x25 ml	F1900006	2022-06-21
TMB	1x25 ml	190705D01	2023-07-30
Sulfuric Acid 0,45M	1x6 ml	F1900840	2023-12-23

Analytical Data	Specification	Result
Reactivity	A450 for 100% \geq 1.40	1.73
Calibration Curve and Accuracy	Controls Measured Values within acceptance ranges	Controls Measured Values within acceptance ranges
Blank	< 0.100	0.020
Detection threshold	\leq 5 %	< 1 %

Calibration Curve for information

						Acceptance Range	MV	
Conc.	C	C/2	C/4	C/10	C/20	CI	[72 - 98]	89
OD	1.94	1.38	0.89	0.45	0.27	CII	[37 - 55]	46

MV = Measured value

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

Date of Approval: 2019-11-25

Quality Control Manager:

S. LECOURT

P.O.



Zymutest Protein C

REF RK027A

Assay of Protein C by ELISA / Dosage ELISA de la Protéine C

For in vitro diagnostic use only / Usage diagnostic *in vitro* exclusivement

LOT F1901187



2022-04-02

<u>Values assigned / Valeurs cibles (*)</u>
Calibrator / Calibrateur LOT : F1903013 Concentration : 129 %
Control / Contrôle CI LOT : F1903014 Target value / Valeur cible : 85 % Acceptance range / Domaine d'acceptation : [72 - 98] %
Control / Contrôle CII LOT : F1903015 Target value / Valeur cible : 46 % Acceptance range / Domaine d'acceptation : [37 - 55] %

(*) Standardization / Standardisation : **Calibrator and controls are related to NIBSC SSCLOT 4**

Note: Curve fitting suitable for RK027A using Magellan software (Tecan ©) : second-degree polynomial (**), 4 parameters, 4 parameters marquardt, 5 parameters marquardt, et akima / Les modes d'interpolation adaptés pour RK027A sur le logiciel Magellan (Tecan ©) sont : polynôme de degré 2 (**), 4 paramètres, 4 paramètres marquardt, 5 paramètres marquardt, akima.

(**) Best fit suggested / Mode d'interpolation à favoriser

Approved Date / Date d'Approbation : 2019-11-25

Quality Control Manager / Responsable Contrôle Qualité : S. LECOURT

