



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

CERTIFICATE OF ANALYSIS

Product Description : ZYMUTEST Protein C

Product Code : RK027A

Lot No. : F1701269

Expiration date : 2020-05-22

Components	Quantity	Lot	Expiration Date
Anti (h) Protein C pre-coated plate	12x8 wells	F1701477	2020-05-22
Protein C Standard	3 vials	F1701487	2020-05-23
Protein C Control I	1 vial	F1701488	2020-05-23
Protein C Control II	1 vial	F1701489	2020-05-23
Anti-(h)-Protein C HRP immunoconjugate	3 vials	F1701486	2020-05-25
Sample diluent	2x50 ml	F1701561	2021-06-02
Wash solution	1x50 ml	F1700796	2020-12-28
Conjugate diluent	1x25 ml	F1700772	2020-12-23
TMB	1x25 ml	160816D01	2020-08-30
Sulfuric Acid 0,45M	1x6 ml	F1700902	2021-01-20

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

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

Date of Approval : 2018-01-05

Quality Control Manager :

S.LECOURT
Plo [Signature]



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 F1701269



2020-05-22

<u>Values assigned / Valeurs cibles (*)</u>
Calibrator / Calibrateur LOT : F1701487 Concentration : 123 %
Control / Contrôle CI LOT : F1701488 Target value / Valeur cible : 90 % Acceptance range / Domaine d'acceptation : [77 - 104] %
Control / Contrôle CII LOT : F1701489 Target value / Valeur cible : 45 % Acceptance range / Domaine d'acceptation : [36 - 54] %

(*) Standardization / Standardisation : calibrator and controls are calibrated against SSC / ISTH Secondary coagulation standard lot #4 qualified against international standard from NIBSC 02/342

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 : 2018-01-05

Quality Control Manager / Responsable Contrôle Qualité : S.LECOURT