



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

CERTIFICATE OF ANALYSIS

Product Description : ZYMUTEST PF4

Product Code : RK006A

Lot No. : F1800080

Expiration date : 2020-06-30

Components	Quantity	Lot	Expiration Date
PF4 pre-coated plate	12x8 wells	F1800047	2020-07-12
PF4 Standard	3 vials	F1800014	2020-06-30
PF4 Control I	1 vial	F1800077	2020-07-12
PF4 Control II	1 vial	F1800078	2020-07-12
PF4 HRP immunoconjugate	3 vials	F1800116	2020-07-20
PF4 Sample diluent	2x50 ml	F1800143	2020-07-25
Wash solution	1x50 ml	F1701244	2021-04-06
Conjugate diluent	1x25 ml	F1700906	2021-01-27
TMB	1x25 ml	161208D01	2020-12-31
Sulfuric Acid 0,45M	1x6 ml	F1700902	2021-01-20

Analytical Data	Specification	Result
Reactivity	A450 for 8 IU/ml \geq 1.70	PASS
Calibration Curve and Accuracy	Controls Measured Values within acceptance ranges	PASS
Blank	< 0.100	PASS
Detection threshold	\leq 0.5 IU/ml	< 0,1

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

Date of Approval : 2018-02-15

Quality Control Manager :

S.LECOURT



ZYMUTEST PF4

REF RK006A

Assay of Platelet Factor 4 by ELISA / Dosage ELISA du Facteur Plaquettaire 4

For in vitro use only / Utilisation in vitro exclusivement - For research use only / Uniquement à usage de recherche

LOT F1800080



2020-06-30

<u>Values assigned / Valeurs cibles (*)</u>
Calibrator / Calibrateur LOT : F1800014 Concentration : 10.7 ng/mL (UI/mL / IU/mL)
Control / Contrôle CI LOT : F1800077 Target value / Valeur cible : 13.4 ng/mL (UI/mL / IU/mL) Acceptance range / Domaine d'acceptation : [12.1 - 14.7] ng/mL (UI/mL / IU/mL)
Control / Contrôle CII LOT : F1800078 Target value / Valeur cible : 2.5 ng/mL (UI/mL / IU/mL) Acceptance range / Domaine d'acceptation : [2.1 - 2.9] ng/mL (UI/mL / IU/mL)

(*) Standardization / Standardisation : calibrator and controls are qualified against internal standard itself qualified against WHO IS 83/505.

Note: Curve fitting suitable for RK006A using Magellan software (Tecan ®) : second-degree polynomial (**), 4 parameters, 4 parameters marquardt, 5 parameters marquardt, cubic spline, akima. / Les modes d'interpolation adaptés pour RK006A sur le logiciel Magellan (Tecan ®) sont : polynôme de degré 2 (**), 4 paramètres, 4 paramètres marquardt, 5 paramètres marquardt, spline cubique, akima.

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

Approved Date / Date d'Approbation : 2018-02-15

Quality Control Manager / Responsable Contrôle Qualité : S.LECOURT