



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

CERTIFICATE OF ANALYSIS

Product Description : ZYMUTEST FACTOR IX

Product Code : RK032A

Lot No. : F1701554

Expiration date : 2020-05-24

Components	Quantity	Lot	Expiration Date
Anti (h) Factor IX pre-coated plate	12x8 wells	F1701478	2020-05-24
Factor IX standard	3 vials	F1700945	2021-02-03
Factor IX Control I	1 vial	F1700946	2021-02-03
Factor IX Control II	1 vial	F1700947	2021-02-03
Anti-(h)-Factor IX HRP immunoconjugate	3 vials	F1800024	2020-06-26
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 % ≥ 1.50	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 : 2018-01-31

Quality Control Manager : **S.LECOURT**

F820-11-ZY-032A-v8



Zymutest Factor IX / *Facteur IX*

REF RK032A

Factor IX Antigen / *Facteur IX Antigène*

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

LOT F1701554



2020-05-24

<u>Values assigned / Valeurs cibles (*)</u>
Calibrator / Calibrateur LOT : F1700945 Concentration : 116 %
Control / Contrôle CI LOT : F1700946 Target value / <i>Valeur cible</i> : 68 % Acceptance range / <i>Domaine d'acceptation</i> : [58 - 78] %
Control / Contrôle CII LOT : F1700947 Target value / <i>Valeur cible</i> : 28 % Acceptance range / <i>Domaine d'acceptation</i> : [22 - 34] %

(*) Standardization / *Standardisation* : Calibrator and controls are indirectly qualified against International standard from NIBSC (99/826)

Note: Curve fitting suitable for RK032A using Magellan software (Tecan ®) : second-degree polynomial (**), third-degree polynomial (**), 4 parameters, 4 parameters marquardt, 5 parameters marquardt, cubic spline, akima, and point to point / *Les modes d'interpolation adaptés pour RK032A sur le logiciel Magellan (Tecan ®) sont : polynôme de degré 2 (**), polynôme de degré 3 (**), 4 paramètres, 4 paramètres marquardt, 5 paramètres marquardt, spline cubique, akima, et point par point.*

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

Approved Date / *Date d'Approbation* : 2018-01-31

Quality Control Manager / *Responsable Contrôle Qualité* : S.LECOURT