

HYPHEN BioMed
ZAC Neuville Université
155 rue d'Eragny
95000 NEUVILLE SUR OISE
France

Tel: +33.1.34.40.65.10
Fax: +33.1.34.48.72.36
www.hyphen-biomed.com

CERTIFICATE OF ANALYSIS

**ZYMUTEST
FACTOR V**

#RK009A

Lot : F1600461

Expiration date : 2019-06-24

905

ANALYSIS CERTIFICATE

FACTOR V Elisa Kit

Lot : F1600461

CQ release : 28/06/2016

Expiration date : 2019-06-24

| Components | Volume (mL) | Exp. (months) | Lot # | Exp. date |
|---------------------------------|-------------|---------------|-----------|------------|
| Factor V pre-coated plate | 12x8 wells | 42 | F1600470 | 2019-10-08 |
| Plasma Factor V calibrator | 3 vials | 42 | F1600473 | 2019-10-21 |
| Control I | 1 vial | 42 | F1600474 | 2019-10-21 |
| Control II | 1 vial | 42 | F1600475 | 2019-10-21 |
| Anti-(h)-FV-HRP immunoconjugate | 3 vials | 42 | F1600607 | 2019-11-22 |
| Factor V Sample diluent | 2x50 | 42 | F1600472 | 2019-10-21 |
| Wash solution | 1x50 | 42 | F1600026 | 2019-06-24 |
| Factor V Conjugate diluent | 1x25 | 42 | F1600442 | 2019-10-01 |
| TMB | 1x25 | | 150915D02 | 2019-09-30 |
| Sulfuric Acid 0,45 M | 1x6 | | F1600128 | 2019-07-08 |

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| Analytical data | | | | Specifications | |
|--------------------------------------|-------------------------------|-----------------------|------------------------|---|---------------|
| 1. <u>Reactivity</u> | A450 for calibrator at 80 % : | | 1,91 | ≥ 1.50 | |
| | | | | | |
| 2. <u>Calibrator Plasma</u> | Concentration | | 100 % | ≥ 80 % | |
| | CV | | 4,6 % | ≤ 10 % | |
| | | | | | |
| 3. <u>Blank value</u> | A450 for sample diluent : | | 0,085 | < 0.100 | |
| | SD : | | 0,012 | < 0.015 | |
| | | | | | |
| 4. <u>Calibration curve</u> | Curve Fitting : | | | N = 10 | |
| | | Polynomial 3 | | | |
| | | OD | SD | CV (%) | CV (%) |
| | C | 2,107 | 0,080 | 3,8 | <10 |
| | C/2 | 1,524 | 0,056 | 3,7 | <10 |
| | C/4 | 0,973 | 0,050 | 5,1 | <10 |
| | C/10 | 0,503 | 0,024 | 4,7 | <10 |
| C/20 | 0,309 | 0,020 | 6,5 | <10 | |
| 0 | | | | / | |
| 5. <u>Detection threshold</u> | | | Concentration % | Specifications | |
| | | | <1% | ≤ 1 % | |
| 6. <u>Controls</u> | Target value | Measured value | | Confidence range | |
| | % | % | | | |
| | Control I | 64 | 67 | 54 to 74 % | |
| Control II | 36 | 34 | 29 to 43 % | | |
| Comments : | | | | <input checked="" type="checkbox"/> PASSED IN COMPLIANCE | |

Date : 28/06/2016

QC Manager :

S.LECOURT





Zymutest Factor V / Facteur V

REF RK009A

Factor V Antigen / Facteur V Antigène

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

LOT F1600461



2019-06-24

| <u>Values assigned / Valeurs cibles (*)</u> |
|--|
| Calibrator / Calibrateur LOT : F1600473 Concentration : 100 % |
| Control / Contrôle CI LOT : F1600474 Target value / Valeur cible : 64 % Acceptance range / Domaine d'acceptation : [54 – 74] % |
| Control / Contrôle CII LOT : F1600475 Target value / Valeur cible : 36 % Acceptance range / Domaine d'acceptation : [29 – 43] % |

(*) Standardization / Standardisation : Calibrator is calibrated against internal standard related to international standard from NIBSC (lot 03/116 through SSC lot 4)

Note: Curve fitting suitable for RK009A 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 RK009A 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 : 28/06/2016

Quality Control Manager / Responsable Contrôle Qualité : S.LECOURT