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CERTIFICATE OF ANALYSIS

**ZYMUTEST
Factor XIII ELISA kit**

#RK034A

Lot : F1601220

Expiration date : 2019-06-17

200

ANALYSIS CERTIFICATE

Factor XIII ELISA kit

Lot : F1601220

QC release : 2017-02-22

Expiration date : 2019-06-17

| Components | Volume (mL) | Exp. (months) | Lot # | Exp. date |
|------------------------------------|-------------|---------------|-----------|------------|
| Anti (h) FXIII pre-coated plate | 12x8 wells | 42 | F1700159 | 2020-07-20 |
| Plasma FXIII Calibrator | 3 vials | 42 | F1500116 | 2019-06-17 |
| Anti-(h)-FXIII-HRP immunoconjugate | 3 vials | 42 | F1700162 | 2020-07-23 |
| Sample diluent | 2x50 | 30 | F1601300 | 2020-06-15 |
| Wash solution | 1x50 | 42 | F1600895 | 2020-02-17 |
| Conjugate diluent | 1x25 | 42 | F1601097 | 2020-04-08 |
| Plasma FXIII Control I | 1 vial | 42 | F1700136 | 2020-07-16 |
| Plasma FXIII Control II | 1 vial | 42 | F1700137 | 2020-07-16 |
| TMB substrate | 1x25 | | 150915D02 | 2019-09-30 |
| Sulfuric Acid 0,45M | 1x6 | 42 | F1600740 | 2019-12-17 |

Geo

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| | Analytical data | Specifications | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|-----------------|--|--------------------|------------------|----------------|------------------|--------|--------|---|-------|-----------|-----|----|------------|------------|-------|------|------------|----|-----|-----|-------|------|-----|----|-----|------|-------|------|-----|----|-----|------|-------|------|-----|----|-----|---|-------|-------|---|----|-----|--|
| 1. | <u>Reactivity</u> A450 for calibrator at 100% : 1,683 | ≥ 1,00 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 2. | <u>Calibrator Plasma</u> Concentration 140 % CV 3,7 % | ≥ 100 % ≤ 10 % | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 3. | <u>Blank value</u> A450 for sample diluent : 0,105 SD : 0,005 | < 0.150 < 0.015 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 4. | <u>Calibration curve</u> Curve Fitting : polynom degree 3 <table style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 15%;">Conc.</th> <th style="width: 15%;">OD</th> <th style="width: 15%;">SD</th> <th style="width: 15%;">CV (%)</th> <th style="width: 15%;">N ≥ 10</th> <th style="width: 15%;">CV (%)</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">C</td> <td style="text-align: center;">1,864</td> <td style="text-align: center;">0,08</td> <td style="text-align: center;">4,4</td> <td style="text-align: center;">10</td> <td style="text-align: center;"><10</td> </tr> <tr> <td style="text-align: center;">C/2</td> <td style="text-align: center;">1,452</td> <td style="text-align: center;">0,05</td> <td style="text-align: center;">3,1</td> <td style="text-align: center;">10</td> <td style="text-align: center;"><10</td> </tr> <tr> <td style="text-align: center;">C/4</td> <td style="text-align: center;">0,944</td> <td style="text-align: center;">0,03</td> <td style="text-align: center;">3,0</td> <td style="text-align: center;">10</td> <td style="text-align: center;"><10</td> </tr> <tr> <td style="text-align: center;">C/10</td> <td style="text-align: center;">0,528</td> <td style="text-align: center;">0,03</td> <td style="text-align: center;">5,9</td> <td style="text-align: center;">10</td> <td style="text-align: center;"><10</td> </tr> <tr> <td style="text-align: center;">C/20</td> <td style="text-align: center;">0,321</td> <td style="text-align: center;">0,02</td> <td style="text-align: center;">5,2</td> <td style="text-align: center;">10</td> <td style="text-align: center;"><10</td> </tr> <tr> <td style="text-align: center;">0</td> <td style="text-align: center;">0,105</td> <td style="text-align: center;">0,005</td> <td style="text-align: center;">/</td> <td style="text-align: center;">10</td> <td style="text-align: center;"><10</td> </tr> </tbody> </table> | Conc. | OD | SD | CV (%) | N ≥ 10 | CV (%) | C | 1,864 | 0,08 | 4,4 | 10 | <10 | C/2 | 1,452 | 0,05 | 3,1 | 10 | <10 | C/4 | 0,944 | 0,03 | 3,0 | 10 | <10 | C/10 | 0,528 | 0,03 | 5,9 | 10 | <10 | C/20 | 0,321 | 0,02 | 5,2 | 10 | <10 | 0 | 0,105 | 0,005 | / | 10 | <10 | |
| Conc. | OD | SD | CV (%) | N ≥ 10 | CV (%) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| C | 1,864 | 0,08 | 4,4 | 10 | <10 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| C/4 | 0,944 | 0,03 | 3,0 | 10 | <10 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| C/10 | 0,528 | 0,03 | 5,9 | 10 | <10 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| C/20 | 0,321 | 0,02 | 5,2 | 10 | <10 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 0 | 0,105 | 0,005 | / | 10 | <10 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 5. | <u>Detection threshold</u> Concentration % <1 | ≤ 10% | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 6. | <table style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 30%;"><u>Controls</u></th> <th style="width: 20%;">Target value</th> <th style="width: 20%;">Measured value</th> <th style="width: 30%;">Acceptance range</th> </tr> <tr> <td></td> <td style="text-align: center;">%</td> <td style="text-align: center;">%</td> <td></td> </tr> </thead> <tbody> <tr> <td>Control I</td> <td style="text-align: center;">73</td> <td style="text-align: center;">78</td> <td style="text-align: center;">62 to 84 %</td> </tr> <tr> <td>Control II</td> <td style="text-align: center;">30</td> <td style="text-align: center;">32</td> <td style="text-align: center;">24 to 36 %</td> </tr> </tbody> </table> | <u>Controls</u> | Target value | Measured value | Acceptance range | | % | % | | Control I | 73 | 78 | 62 to 84 % | Control II | 30 | 32 | 24 to 36 % | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| <u>Controls</u> | Target value | Measured value | Acceptance range | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | % | % | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Control I | 73 | 78 | 62 to 84 % | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Control II | 30 | 32 | 24 to 36 % | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 7. | <u>Performances</u> Measured value Normal Plasmas N = 12 106 FXIII deficient plasma 3,3 | > 60% ≤ 10% | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |

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|-------------------|---|
| <u>Comments :</u> | <input checked="" type="checkbox"/> PASSED IN COMPLIANCE |
|-------------------|---|

Date : 2017-02-22

QC Manager : S. LECOURT



Zymutest Factor XIII-A / Facteur XIII-A

REF RK034A

Factor XIII - A / Facteur XIII - A

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

LOT F1601220

 2019-06-17

| <u>Values assigned / Valeurs cibles (*)</u> |
|--|
| Calibrator / Calibrateur LOT : F1500116 Concentration : 140 % |
| Control / Contrôle CI LOT : F1700136 Target value / Valeur cible : 73 % Acceptance range / Domaine d'acceptation : [62 - 84] % |
| Control / Contrôle CII LOT : F1700137 Target value / Valeur cible : 30 % Acceptance range / Domaine d'acceptation : [24 - 36] % |

(*) Standardization / Standardisation : Calibrator and controls are calibrated against internal standard related to internal standard from NIBSC (lot 02/206)

Note: Curve fitting suitable for RK034A using Magellan software (Tecan ©) :third-degree polynomial (**), 4 parameters, 4 parameters marquardt, 5 parameters marquardt / Les modes d'interpolation adaptés pour RK034A sur le logiciel Magellan (Tecan ©) sont : polynôme de degré 3 (**), 4 paramètres, 4 paramètres marquardt, 5 paramètres marquardt.

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

Approved Date / Date d'Approbation : 2017-02-22

Quality Control Manager / Responsable Contrôle Qualité : S.LECOURT