

Qualitätskontrollzertifikat / Quality Control Certificate

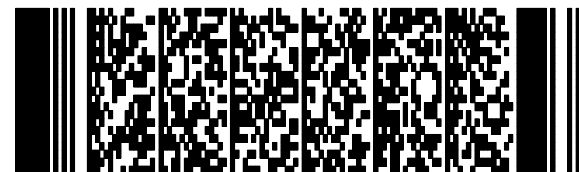
Kitcharge / Lot SAI.EU IFU-Version 132-12

31.01.2018

Verw. bis / Exp. 2019-12

Prüfdatum /

Date of control



| Verwendete Reagenzien / Reagents used              | Lot      | Standard                  |                                     | Standard Kurve / Standard curve |           |
|--|----------|---------------------------|-------------------------------------|---------------------------------|-----------|
| Teststreifen / Antigen coated strips               | SMH.BV   | Ref.- Werte / Ref. Values | Gültigkeitsbereich / Validity Range |                                 | Parameter |
| Standardserum / Standard serum                     | SAI.AF   | OD 0,84                   | OD 0,42 - 1,43                      |                                 | A -0,015  |
| Negativ Kontrolle / Negative control               | SAI.AE   |                           |                                     |                                 | B 0,857   |
| Konjugat / Conjugate                               | SAI.CG++ | Units 64,9 U/ml           |                                     |                                 | C 5,960   |
|  |          |                           |                                     |                                 | D 4,795   |
| Quantifizierungsgrenzen / Limits of quantification |          | U/ml                      | 30                                  | -                               | 1000      |
| Grenzwertbereich / Borderline range                |          | U/ml                      | 50                                  | -                               | 70        |

| OD Bereich / OD Range 405 nm, Standardserum / Standard serum |             |             |             |             |             |             |             |             |             |                 |  |
|--|-------------|-------------|-------------|-------------|-------------|-------------|-------------|-------------|-------------|-----------------|--|
| 0,42 - 0,46  | 0,47 - 0,52 | 0,53 - 0,57 | 0,58 - 0,62 | 0,63 - 0,67 | 0,68 - 0,73 | 0,74 - 0,78 | 0,79 - 0,83 | 0,84        | U/ml        | Interpretation  |  |
| < 0,36   | < 0,41      | < 0,45      | < 0,49      | < 0,53      | < 0,58      | < 0,62      | < 0,66      | < 0,69      | < 50,0      | neg             |  |
| 0,36 - 0,47  | 0,41 - 0,52 | 0,45 - 0,58 | 0,49 - 0,63 | 0,53 - 0,69 | 0,58 - 0,75 | 0,62 - 0,80 | 0,66 - 0,86 | 0,69 - 0,89 | 50,0 - 70,0 | gw / borderline |  |
| > 0,47   | > 0,52      | > 0,58      | > 0,63      | > 0,69      | > 0,75      | > 0,80      | > 0,86      | > 0,89      | > 70,0      | pos             |  |

| OD Bereich / OD Range 405 nm, Standardserum / Standard serum |             |             |             |             |             |             |             |             |             |                 |  |
|--|-------------|-------------|-------------|-------------|-------------|-------------|-------------|-------------|-------------|-----------------|--|
| U/ml   | 0,84        | 0,85 - 0,91 | 0,92 - 0,99 | 1,00 - 1,06 | 1,07 - 1,13 | 1,14 - 1,21 | 1,22 - 1,28 | 1,29 - 1,35 | 1,36 - 1,43 | Interpretation  |  |
| < 50,0   | < 0,69      | < 0,72      | < 0,78      | < 0,85      | < 0,91      | < 0,97      | < 1,03      | < 1,09      | < 1,15      | neg             |  |
| 50,0 - 70,0  | 0,69 - 0,89 | 0,72 - 0,93 | 0,78 - 1,01 | 0,85 - 1,09 | 0,91 - 1,17 | 0,97 - 1,25 | 1,03 - 1,32 | 1,09 - 1,40 | 1,15 - 1,48 | gw / borderline |  |
| > 70,0   | > 0,89      | > 0,93      | > 1,01      | > 1,09      | > 1,17      | > 1,25      | > 1,32      | > 1,40      | > 1,48      | pos             |  |

Formeln für spezielle Auswertesysteme  
Special case formulas

OD = 1,055 x MV(STD) entspricht oberem cut-off/ corresponds to upper cut-off  
 OD = 0,826 x MV(STD) entspricht unterem cut-off/ corresponds to lower cut-off  
 Concentration= exp(5,96-In(4,81/(MV(Sample) x0,84/ MV(STD)+0,015)-1)/0,857)

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**Zusätzliche Barcodes mit Formeln für / Additional Barcodes with formulas for  
Revelation™ DSX / DS-Matrix™****4PS- Formel / 4PS-formula**
$$\exp(5.960 - \ln(4.810 / (\text{Sample} * 0.840 / S + 0.015) - 1) / 0.857)$$
**Gültigkeitsbereich / Validity Range**
$$0.420 \leq S1 \leq 1.428$$
**If OD Sample < Parameter A**
$$\text{if } Ti < (-0.015 * (S1 / 0.840)) \text{ then } Ti = (-0.015 + 0.001) * (S1 / 0.840)$$
**If OD Sample > Parameter D**
$$\text{if } Ti > (4.795 * (S1 / 0.840)) \text{ then } Ti = (4.795 - 0.001) * (S1 / 0.840)$$
**If OD Negative control < Parameter A**
$$\text{if } NC1 < (-0.015 * (S1 / 0.840)) \text{ then } NCi = (-0.015 + 0.001) * (S1 / 0.840)$$
