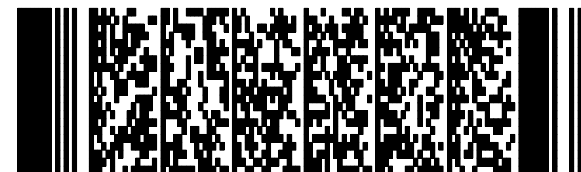


Qualitätskontrollzertifikat / Quality Control Certificate



Kitcharge / Lot EM0216 IFU-Version 116-15
 Verw. bis / Exp. 2023-10-31 **!New!**

26.10.2021

Prüfdatum /

Date of control

| Verwendete Reagenzien / Reagents used | Lot | Standard | Standard Kurve / Standard curve |
|--|----------|---------------------------|---|
| Teststreifen / Antigen coated strips | ECM0430 | Ref.- Werte / Ref. Values | Parameter A -0,016 B 0,966 C 3,847 D 2,406 |
| Standardserum / Standard serum | ECM0446 | OD 0,96 | |
| Negativ Kontrolle / Negative control | ECM0445 | | |
| Konjugat / Conjugate | KJM021++ | Units 31,2 U/ml | |
| Quantifizierungsgrenzen / Limits of quantification | | U/ml 5 - 500 | |
| Grenzwertbereich / Borderline range | | U/ml 20 - 30 | |

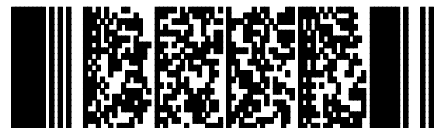
| OD Bereich / OD Range 405 nm, Standardserum / Standard serum | | | | | | | | | | | |
|--|-------------|-------------|-------------|-------------|-------------|-------------|-------------|-------------|-------------|-----------------|--|
| 0,48 - 0,53 | 0,54 - 0,59 | 0,60 - 0,65 | 0,66 - 0,71 | 0,72 - 0,77 | 0,78 - 0,83 | 0,84 - 0,89 | 0,90 - 0,95 | 0,96 | U/ml | Interpretation | |
| < 0,38 | < 0,42 | < 0,47 | < 0,51 | < 0,56 | < 0,60 | < 0,65 | < 0,69 | < 0,72 | < 20,0 | neg | |
| 0,38 - 0,49 | 0,42 - 0,55 | 0,47 - 0,61 | 0,51 - 0,67 | 0,56 - 0,73 | 0,60 - 0,79 | 0,65 - 0,85 | 0,69 - 0,91 | 0,72 - 0,94 | 20,0 - 30,0 | gw / borderline | |
| > 0,49 | > 0,55 | > 0,61 | > 0,67 | > 0,73 | > 0,79 | > 0,85 | > 0,91 | > 0,94 | > 30,0 | pos | |

| OD Bereich / OD Range 405 nm, Standardserum / Standard serum | | | | | | | | | | | |
|--|-------------|-------------|-------------|-------------|-------------|-------------|-------------|-------------|-------------|-----------------|--|
| U/ml | 0,96 | 0,97 - 1,04 | 1,05 - 1,13 | 1,14 - 1,21 | 1,22 - 1,30 | 1,31 - 1,38 | 1,39 - 1,46 | 1,47 - 1,55 | 1,56 - 1,63 | Interpretation | |
| < 20,0 | < 0,72 | < 0,76 | < 0,82 | < 0,88 | < 0,94 | < 1,01 | < 1,07 | < 1,13 | < 1,20 | neg | |
| 20,0 - 30,0 | 0,72 - 0,94 | 0,76 - 0,99 | 0,82 - 1,07 | 0,88 - 1,15 | 0,94 - 1,23 | 1,01 - 1,32 | 1,07 - 1,40 | 1,13 - 1,48 | 1,20 - 1,56 | gw / borderline | |
| > 30,0 | > 0,94 | > 0,99 | > 1,07 | > 1,15 | > 1,23 | > 1,32 | > 1,40 | > 1,48 | > 1,56 | pos | |

Formeln für spezielle Auswertesysteme
 Special case formulas

OD = 0,977 x MV(STD) entspricht oberem cut-off/ corresponds to upper cut-off
 OD = 0,754 x MV(STD) entspricht unterem cut-off/ corresponds to lower cut-off
 Concentration= exp(3,847-ln(2,422/(MV(Sample) x0,96/ MV(STD)+0,016)-1)/0,966)

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**Zusätzliche Barcodes mit Formeln für / Additional Barcodes with formulas for
Revelation™ DSX / DS-Matrix™****4PS- Formel / 4PS-formula**
$$\exp(3.847 - \ln(2.422 / (\text{Sample}^{0.960} / S + 0.016) - 1) / 0.966)$$
**Gültigkeitsbereich / Validity Range**
$$0.480 \leq S1 \leq 1.632$$
**If OD Sample < Parameter A**
$$\text{if } Ti < (-0.016 * (S1 / 0.960)) \text{ then } Ti = (-0.016 + 0.001) * (S1 / 0.960)$$
**If OD Sample > Parameter D**
$$\text{if } Ti > (2.406 * (S1 / 0.960)) \text{ then } Ti = (2.406 - 0.001) * (S1 / 0.960)$$
**If OD Negative control < Parameter A**
$$\text{if } NC1 < (-0.016 * (S1 / 0.960)) \text{ then } NCi = (-0.016 + 0.001) * (S1 / 0.960)$$
