

Qualitätskontrollzertifikat / Quality Control Certificate



Kitcharge / Lot EP0169 IFU-Version 134-17

02.07.2024

Verw. bis / Exp. 2026-03-31

Prüfdatum /

Date of control

| Verwendete Reagenzien / Reagents used | Lot | Standard | | Standard Kurve / Standard curve | | |
|--|---------|---------------------------|-------------------------------------|---------------------------------|-----------|---------|
| Teststreifen / Antigen coated strips | ECP0079 | Ref.- Werte / Ref. Values | Gültigkeitsbereich / Validity Range | | Parameter | A 0,052 |
| Standardserum / Standard serum | ECP0073 | OD 0,87 | OD 0,44 - 1,48 | | B | 1,217 |
| Negativ Kontrolle / Negative control | ECP0072 | | | | C | 3,970 |
| Konjugat / Conjugate | KJP073+ | Units 17,6 U/ml | | | D | 4,008 |
| Quantifizierungsgrenzen / Limits of quantification | | U/ml | 4 | - | 150 | |
| Grenzwertbereich / Borderline range | | U/ml | 10 | - | 15 | |

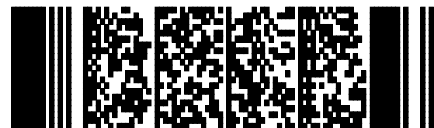
| OD Bereich / OD Range 405 nm, Standardserum / Standard serum | | | | | | | | | | | |
|--|-------------|-------------|-------------|-------------|-------------|-------------|-------------|-------------|-------------|--|-----------------|
| 0,44 - 0,48 | 0,49 - 0,53 | 0,54 - 0,59 | 0,60 - 0,64 | 0,65 - 0,70 | 0,71 - 0,75 | 0,76 - 0,81 | 0,82 - 0,86 | 0,87 | U/ml | | Interpretation |
| < 0,27 | < 0,30 | < 0,33 | < 0,36 | < 0,40 | < 0,43 | < 0,46 | < 0,49 | < 0,51 | < 10,0 | | neg |
| 0,27 - 0,39 | 0,30 - 0,44 | 0,33 - 0,49 | 0,36 - 0,53 | 0,40 - 0,58 | 0,43 - 0,63 | 0,46 - 0,68 | 0,49 - 0,72 | 0,51 - 0,75 | 10,0 - 15,0 | | gw / borderline |
| > 0,39 | > 0,44 | > 0,49 | > 0,53 | > 0,58 | > 0,63 | > 0,68 | > 0,72 | > 0,75 | > 15,0 | | pos |

| OD Bereich / OD Range 405 nm, Standardserum / Standard serum | | | | | | | | | | | |
|--|-------------|-------------|-------------|-------------|-------------|-------------|-------------|-------------|-------------|--|-----------------|
| U/ml | 0,87 | 0,88 - 0,95 | 0,96 - 1,02 | 1,03 - 1,10 | 1,11 - 1,17 | 1,18 - 1,25 | 1,26 - 1,33 | 1,34 - 1,40 | 1,41 - 1,48 | | Interpretation |
| < 10,0 | < 0,51 | < 0,54 | < 0,58 | < 0,62 | < 0,67 | < 0,71 | < 0,76 | < 0,80 | < 0,85 | | neg |
| 10,0 - 15,0 | 0,51 - 0,75 | 0,54 - 0,79 | 0,58 - 0,85 | 0,62 - 0,92 | 0,67 - 0,98 | 0,71 - 1,05 | 0,76 - 1,12 | 0,80 - 1,18 | 0,85 - 1,25 | | gw / borderline |
| > 15,0 | > 0,75 | > 0,79 | > 0,85 | > 0,92 | > 0,98 | > 1,05 | > 1,12 | > 1,18 | > 1,25 | | pos |

Formeln für spezielle Auswertesysteme
Special case formulas

OD = 0,865 x MV(STD) entspricht oberem cut-off/ corresponds to upper cut-off
 OD = 0,588 x MV(STD) entspricht unterem cut-off/ corresponds to lower cut-off
 Concentration= exp(3,97-In(3,956/(MV(Sample) x0,87/ MV(STD)-0,052)-1)/1,217)

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**Zusätzliche Barcodes mit Formeln für / Additional Barcodes with formulas for
Revelation™ DSX / DS-Matrix™****4PS- Formel / 4PS-formula**
$$\exp(3.970 - \ln(3.956 / (\text{Sample}^{0.870} / S - 0.052) - 1) / 1.217)$$
**Gültigkeitsbereich / Validity Range**
$$0.435 \leq S1 \leq 1.479$$
**If OD Sample < Parameter A**
$$\text{if } Ti < (0.052 * (S1 / 0.870)) \text{ then } Ti = (0.052 + 0.001) * (S1 / 0.870)$$
**If OD Sample > Parameter D**
$$\text{if } Ti > (4.008 * (S1 / 0.870)) \text{ then } Ti = (4.008 - 0.001) * (S1 / 0.870)$$
**If OD Negative control < Parameter A**
$$\text{if } NC1 < (0.052 * (S1 / 0.870)) \text{ then } NCi = (0.052 + 0.001) * (S1 / 0.870)$$
