

Qualitätskontrollzertifikat / Quality Control Certificate



Kitcharge / Lot EN0261 IFU-Version 120-20

10.01.2023

Verw. bis / Exp. 2024-12-31

Prüfdatum /

Date of control

| Verwendete Reagenzien / Reagents used              | Lot      | Standard                  | Standard Kurve / Standard curve                     |
|--|----------|---------------------------|---|
| Teststreifen / Antigen coated strips               | ECN0306  | Ref.- Werte / Ref. Values | Parameter A -0,025<br>B 0,887<br>C 4,625<br>D 2,795 |
| Standardserum / Standard serum                     | ECN0629  | OD 1,02                   |   |
| Negativ Kontrolle / Negative control               | ECN0628  |                           |   |
| Konjugat / Conjugate                               | KJN047++ | Units 56,1 IU/ml          |   |
| Quantifizierungsgrenzen / Limits of quantification |          | IU/ml 10 - 1000           |   |
| Grenzwertbereich / Borderline range                |          | IU/ml 40 - 50             |   |

| OD Bereich / OD Range 405 nm, Standardserum / Standard serum |             |             |             |             |             |             |             |             |             |                 |  |
|--|-------------|-------------|-------------|-------------|-------------|-------------|-------------|-------------|-------------|-----------------|--|
| 0,51 - 0,56  | 0,57 - 0,63 | 0,64 - 0,69 | 0,70 - 0,76 | 0,77 - 0,82 | 0,83 - 0,88 | 0,89 - 0,95 | 0,96 - 1,01 | 1,02        | IU/ml       | Interpretation  |  |
| < 0,44   | < 0,49      | < 0,54      | < 0,59      | < 0,64      | < 0,70      | < 0,75      | < 0,80      | < 0,83      | < 40,0      | neg             |  |
| 0,44 - 0,50  | 0,49 - 0,56 | 0,54 - 0,62 | 0,59 - 0,68 | 0,64 - 0,74 | 0,70 - 0,80 | 0,75 - 0,86 | 0,80 - 0,92 | 0,83 - 0,95 | 40,0 - 50,0 | gw / borderline |  |
| > 0,50   | > 0,56      | > 0,62      | > 0,68      | > 0,74      | > 0,80      | > 0,86      | > 0,92      | > 0,95      | > 50,0      | pos             |  |

| OD Bereich / OD Range 405 nm, Standardserum / Standard serum |             |             |             |             |             |             |             |             |             |                 |  |
|--|-------------|-------------|-------------|-------------|-------------|-------------|-------------|-------------|-------------|-----------------|--|
| IU/ml  | 1,02        | 1,03 - 1,11 | 1,12 - 1,20 | 1,21 - 1,29 | 1,30 - 1,38 | 1,39 - 1,47 | 1,48 - 1,56 | 1,57 - 1,64 | 1,65 - 1,73 | Interpretation  |  |
| < 40,0   | < 0,83      | < 0,87      | < 0,94      | < 1,02      | < 1,09      | < 1,16      | < 1,23      | < 1,31      | < 1,38      | neg             |  |
| 40,0 - 50,0  | 0,83 - 0,95 | 0,87 - 1,00 | 0,94 - 1,08 | 1,02 - 1,16 | 1,09 - 1,25 | 1,16 - 1,33 | 1,23 - 1,41 | 1,31 - 1,49 | 1,38 - 1,58 | gw / borderline |  |
| > 50,0   | > 0,95      | > 1,00      | > 1,08      | > 1,16      | > 1,25      | > 1,33      | > 1,41      | > 1,49      | > 1,58      | pos             |  |

Formeln für spezielle Auswertesysteme  
Special case formulas

OD = 0,935 x MV(STD) entspricht oberem cut-off/ corresponds to upper cut-off  
 OD = 0,815 x MV(STD) entspricht unterem cut-off/ corresponds to lower cut-off  
 Concentration= exp(4,625-ln(2,82/(MV(Sample) x1,02/ MV(STD)+0,025)-1)/0,887)

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**Zusätzliche Barcodes mit Formeln für / Additional Barcodes with formulas for  
Revelation™ DSX / DS-Matrix™****4PS- Formel / 4PS-formula**
$$\exp(4.625 - \ln(2.820 / (\text{Sample} * 1.020 / S + 0.025) - 1) / 0.887)$$
**Gültigkeitsbereich / Validity Range**
$$0.510 \leq S1 \leq 1.734$$
**If OD Sample < Parameter A**
$$\text{if } Ti < (-0.025 * (S1 / 1.020)) \text{ then } Ti = (-0.025 + 0.001) * (S1 / 1.020)$$
**If OD Sample > Parameter D**
$$\text{if } Ti > (2.795 * (S1 / 1.020)) \text{ then } Ti = (2.795 - 0.001) * (S1 / 1.020)$$
**If OD Negative control < Parameter A**
$$\text{if } NC1 < (-0.025 * (S1 / 1.020)) \text{ then } NCi = (-0.025 + 0.001) * (S1 / 1.020)$$
