

Qualitätskontrollzertifikat / Quality Control Certificate

Kitcharge / Lot **EM0208** IFU-Version **123-19**  
 Verw. bis / Exp. **2023-09-30** **!New!**

12.10.2021

Prüfdatum /

Date of control



| Verwendete Reagenzien / Reagents used              | Lot             | Standard                  | Standard Kurve / Standard curve  |
|--|-----------------|---------------------------|--|
| Teststreifen / Antigen coated strips               | <b>ECM0417</b>  | Ref.- Werte / Ref. Values | Parameter <b>A 0,059</b><br><b>B 1,086</b><br><b>C 3,588</b><br><b>D 3,431</b> |
| Standardserum / Standard serum                     | <b>ECM0403</b>  | OD <b>0,79</b>            |  |
| Negativ Kontrolle / Negative control               | <b>ECM0402</b>  |                           |  |
| Konjugat / Conjugate                               | <b>KJM024++</b> | Units <b>11,1 U/ml</b>    |  |
| Quantifizierungsgrenzen / Limits of quantification |                 | U/ml <b>2 - 200</b>       |  |
| Grenzwertbereich / Borderline range                |                 | U/ml <b>10 - 15</b>       |  |

| OD Bereich / OD Range 405 nm, Standardserum / Standard serum |             |             |             |             |             |             |             |             |             |                 |
|--|-------------|-------------|-------------|-------------|-------------|-------------|-------------|-------------|-------------|-----------------|
| 0,40 - 0,43  | 0,44 - 0,48 | 0,49 - 0,53 | 0,54 - 0,58 | 0,59 - 0,63 | 0,64 - 0,68 | 0,69 - 0,73 | 0,74 - 0,78 | 0,79        | U/ml        | Interpretation  |
| < 0,38   | < 0,43      | < 0,47      | < 0,52      | < 0,56      | < 0,61      | < 0,66      | < 0,70      | < 0,73      | < 10,0      | neg             |
| 0,38 - 0,52  | 0,43 - 0,59 | 0,47 - 0,65 | 0,52 - 0,71 | 0,56 - 0,77 | 0,61 - 0,83 | 0,66 - 0,90 | 0,70 - 0,96 | 0,73 - 1,00 | 10,0 - 15,0 | gw / borderline |
| > 0,52   | > 0,59      | > 0,65      | > 0,71      | > 0,77      | > 0,83      | > 0,90      | > 0,96      | > 1,00      | > 15,0      | pos             |

| OD Bereich / OD Range 405 nm, Standardserum / Standard serum |             |             |             |             |             |             |             |             |             |                 |
|--|-------------|-------------|-------------|-------------|-------------|-------------|-------------|-------------|-------------|-----------------|
| U/ml   | 0,79        | 0,80 - 0,86 | 0,87 - 0,93 | 0,94 - 1,00 | 1,01 - 1,07 | 1,08 - 1,14 | 1,15 - 1,20 | 1,21 - 1,27 | 1,28 - 1,34 | Interpretation  |
| < 10,0   | < 0,73      | < 0,76      | < 0,83      | < 0,89      | < 0,96      | < 1,02      | < 1,08      | < 1,15      | < 1,21      | neg             |
| 10,0 - 15,0  | 0,73 - 1,00 | 0,76 - 1,05 | 0,83 - 1,13 | 0,89 - 1,22 | 0,96 - 1,31 | 1,02 - 1,39 | 1,08 - 1,48 | 1,15 - 1,57 | 1,21 - 1,66 | gw / borderline |
| > 15,0   | > 1,00      | > 1,05      | > 1,13      | > 1,22      | > 1,31      | > 1,39      | > 1,48      | > 1,57      | > 1,66      | pos             |

Formeln für spezielle Auswertesysteme  
 Special case formulas

OD = **1,260** x MV(STD) entspricht oberem cut-off/ corresponds to upper cut-off  
 OD = **0,922** x MV(STD) entspricht unterem cut-off/ corresponds to lower cut-off  
 Concentration= exp(3,588-ln(3,372/(MV(Sample) x0,79/ MV(STD)-0,059)-1)/1,086)

15 **Institut Virion\Serion GmbH**  
 10 **Friedrich-Bergius-Ring 19**  
**D-97076 Würzburg**

**Zusätzliche Barcodes mit Formeln für / Additional Barcodes with formulas for  
Revelation™ DSX / DS-Matrix™****4PS- Formel / 4PS-formula**
$$\exp(3.588 - \ln(3.372 / (\text{Sample} * 0.790 / S - 0.059) - 1) / 1.086)$$
**Gültigkeitsbereich / Validity Range**
$$0.395 \leq S1 \leq 1.343$$
**If OD Sample < Parameter A**
$$\text{if } Ti < (0.059 * (S1 / 0.790)) \text{ then } Ti = (0.059 + 0.001) * (S1 / 0.790)$$
**If OD Sample > Parameter D**
$$\text{if } Ti > (3.431 * (S1 / 0.790)) \text{ then } Ti = (3.431 - 0.001) * (S1 / 0.790)$$
**If OD Negative control < Parameter A**
$$\text{if } NC1 < (0.059 * (S1 / 0.790)) \text{ then } NCi = (0.059 + 0.001) * (S1 / 0.790)$$
