

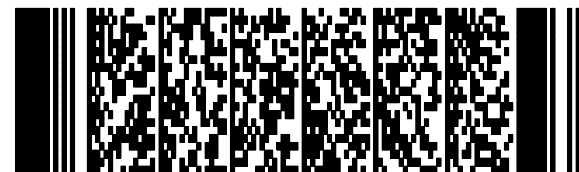
Qualitätskontrollzertifikat / Quality Control Certificate

Kitcharge / Lot            EM0205    IFU-Version    104-20  
 Verw. bis / Exp.            2023-09-30                      **!New!**

11.10.2021

Prüfdatum /

Date of control



Verwendete Reagenzien / Reagents used	Lot	Standard	Standard Kurve / Standard curve
Teststreifen / Antigen coated strips	ECM0350	Ref.- Werte / Ref. Values	Parameter <b>A</b> <b>-0,051</b> <b>B</b> <b>0,722</b> <b>C</b> <b>4,726</b> <b>D</b> <b>3,817</b>
Standardserum / Standard serum	ECM0427	OD 0,93	
Negativ Kontrolle / Negative control	ECM0426		
Konjugat / Conjugate	KJM020+	Units 25,3 U/ml	
Quantifizierungsgrenzen / Limits of quantification		U/ml    5    -    1000	
Grenzwertbereich / Borderline range		U/ml    35    -    50	

OD Bereich / OD Range 405 nm, Standardserum / Standard serum										
0,47 - 0,51	0,52 - 0,57	0,58 - 0,63	0,64 - 0,69	0,70 - 0,75	0,76 - 0,80	0,81 - 0,86	0,87 - 0,92	0,93	U/ml	Interpretation
< 0,58	< 0,65	< 0,72	< 0,79	< 0,86	< 0,93	< 1,00	< 1,07	< 1,11	< 35,0	neg
0,58 - 0,70	0,65 - 0,78	0,72 - 0,87	0,79 - 0,95	0,86 - 1,03	0,93 - 1,12	1,00 - 1,20	1,07 - 1,28	1,11 - 1,33	35,0 - 50,0	gw / borderline
> 0,70	> 0,78	> 0,87	> 0,95	> 1,03	> 1,12	> 1,20	> 1,28	> 1,33	> 50,0	pos

OD Bereich / OD Range 405 nm, Standardserum / Standard serum										
U/ml	0,93	0,94 - 1,01	1,02 - 1,09	1,10 - 1,17	1,18 - 1,26	1,27 - 1,34	1,35 - 1,42	1,43 - 1,50	1,51 - 1,58	Interpretation
< 35,0	< 1,11	< 1,16	< 1,26	< 1,36	< 1,46	< 1,55	< 1,65	< 1,75	< 1,84	neg
35,0 - 50,0	1,11 - 1,33	1,16 - 1,40	1,26 - 1,51	1,36 - 1,63	1,46 - 1,74	1,55 - 1,86	1,65 - 1,98	1,75 - 2,09	1,84 - 2,21	gw / borderline
> 50,0	> 1,33	> 1,40	> 1,51	> 1,63	> 1,74	> 1,86	> 1,98	> 2,09	> 2,21	pos

Formeln für spezielle Auswertesysteme  
 Special case formulas

OD = 1,431 x MV(STD) entspricht oberem cut-off/ corresponds to upper cut-off  
 OD = 1,195 x MV(STD) entspricht unterem cut-off/ corresponds to lower cut-off  
 Concentration= exp(4,726-ln(3,868/(MV(Sample) x0,93/ MV(STD)+0,051)-1)/0,722)

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       D-97076 Würzburg

**Zusätzliche Barcodes mit Formeln für / Additional Barcodes with formulas for  
Revelation™ DSX / DS-Matrix™****4PS- Formel / 4PS-formula**
$$\exp(4.726 - \ln(3.868 / (\text{Sample} * 0.930 / S + 0.051) - 1) / 0.722)$$
**Gültigkeitsbereich / Validity Range**
$$0.465 \leq S1 \leq 1.581$$
**If OD Sample < Parameter A**
$$\text{if } Ti < (-0.051 * (S1 / 0.930)) \text{ then } Ti = (-0.051 + 0.001) * (S1 / 0.930)$$
**If OD Sample > Parameter D**
$$\text{if } Ti > (3.817 * (S1 / 0.930)) \text{ then } Ti = (3.817 - 0.001) * (S1 / 0.930)$$
**If OD Negative control < Parameter A**
$$\text{if } NC1 < (-0.051 * (S1 / 0.930)) \text{ then } NCi = (-0.051 + 0.001) * (S1 / 0.930)$$
