

SERION ELISA classic ESR138G

YERSINIA IgG

SDK.BA

Qualitätskontrollzertifikat / Quality Control Certificate

Kitcharge / Lot

SDK.BA

IFU-Version 138-14

12.04.2019

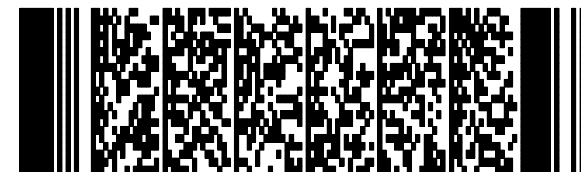
Verw. bis / Exp.

2021-03

!New!

Prüfdatum /

Date of control



| Verwendete Reagenzien / Reagents used | Lot | Standard | | Standard Kurve / Standard curve | | |
|---|------------------|---------------------------|-------------------------------------|---------------------------------|------------|----------------|
| Teststreifen / Antigen coated strips | SBK.CY | Ref.- Werte / Ref. Values | Gültigkeitsbereich / Validity Range | | Parameter | A 0,009 |
| Standardserum / Standard serum | SCK.AG | OD 0,98 | OD 0,49 - 1,67 | | B | 0,986 |
| Negativ Kontrolle / Negative control | SCK.AF | | | | C | 4,426 |
| Konjugat / Conjugate | SCK.CP+++ | Units 62,5 U/ml | | | D | 2,273 |
| Quantifizierungsgrenzen / Limits of quantification | | U/ml | 5 | - | 500 | |
| Grenzwertbereich / Borderline range | | U/ml | 10 | - | 15 | |

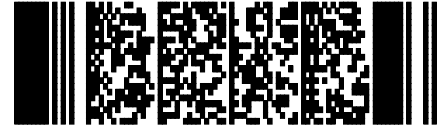
| OD Bereich / OD Range 405 nm, Standardserum / Standard serum | | | | | | | | | | | |
|--|-------------|-------------|-------------|-------------|-------------|-------------|-------------|-------------|-------------|-----------------|--|
| 0,49 - 0,54 | 0,55 - 0,60 | 0,61 - 0,66 | 0,67 - 0,73 | 0,74 - 0,79 | 0,80 - 0,85 | 0,86 - 0,91 | 0,92 - 0,97 | 0,98 | U/ml | Interpretation | |
| < 0,14 | < 0,15 | < 0,17 | < 0,19 | < 0,20 | < 0,22 | < 0,23 | < 0,25 | < 0,26 | < 10,0 | neg | |
| 0,14 - 0,19 | 0,15 - 0,21 | 0,17 - 0,23 | 0,19 - 0,26 | 0,20 - 0,28 | 0,22 - 0,30 | 0,23 - 0,32 | 0,25 - 0,35 | 0,26 - 0,36 | 10,0 - 15,0 | gw / borderline | |
| > 0,19 | > 0,21 | > 0,23 | > 0,26 | > 0,28 | > 0,30 | > 0,32 | > 0,35 | > 0,36 | > 15,0 | pos | |

| OD Bereich / OD Range 405 nm, Standardserum / Standard serum | | | | | | | | | | | |
|--|-------------|-------------|-------------|-------------|-------------|-------------|-------------|-------------|-------------|-----------------|--|
| U/ml | 0,98 | 0,99 - 1,07 | 1,08 - 1,15 | 1,16 - 1,24 | 1,25 - 1,32 | 1,33 - 1,41 | 1,42 - 1,49 | 1,50 - 1,58 | 1,59 - 1,67 | Interpretation | |
| < 10,0 | < 0,26 | < 0,27 | < 0,30 | < 0,32 | < 0,34 | < 0,36 | < 0,39 | < 0,41 | < 0,43 | neg | |
| 10,0 - 15,0 | 0,26 - 0,36 | 0,27 - 0,38 | 0,30 - 0,41 | 0,32 - 0,44 | 0,34 - 0,47 | 0,36 - 0,50 | 0,39 - 0,54 | 0,41 - 0,57 | 0,43 - 0,60 | gw / borderline | |
| > 15,0 | > 0,36 | > 0,38 | > 0,41 | > 0,44 | > 0,47 | > 0,50 | > 0,54 | > 0,57 | > 0,60 | pos | |

Formeln für spezielle Auswertesysteme
Special case formulas

OD = **0,368** x MV(STD) entspricht oberem cut-off/ corresponds to upper cut-off
 OD = **0,263** x MV(STD) entspricht unterem cut-off/ corresponds to lower cut-off
 Concentration= exp(4,426-ln(2,264/(MV(Sample) x0,98/ MV(STD)-0,009)-1)/0,986)

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**Zusätzliche Barcodes mit Formeln für / Additional Barcodes with formulas for
Revelation™ DSX / DS-Matrix™****4PS- Formel / 4PS-formula**
$$\exp(4.426 - \ln(2.264 / (\text{Sample} * 0.980 / S - 0.009) - 1) / 0.986)$$
**Gültigkeitsbereich / Validity Range**
$$0.490 \leq S1 \leq 1.666$$
**If OD Sample < Parameter A**
$$\text{if } Ti < (0.009 * (S1 / 0.980)) \text{ then } Ti = (0.009 + 0.001) * (S1 / 0.980)$$
**If OD Sample > Parameter D**
$$\text{if } Ti > (2.273 * (S1 / 0.980)) \text{ then } Ti = (2.273 - 0.001) * (S1 / 0.980)$$
**If OD Negative control < Parameter A**
$$\text{if } NC1 < (0.009 * (S1 / 0.980)) \text{ then } NCi = (0.009 + 0.001) * (S1 / 0.980)$$
