

SERION ELISA *classic*

Francisella tularensis IgG/IgM



Instructions - English

(Version V 142.5)

virion\serion

	<u>Updates</u>
Current version Nr.:	V 142.5
Previous version:	V 142.4
Update in section:	general Update

SERION ELISA *classic* Francisella tularensis IgG/IgM

CONTENTS

- 1 INTENDED USE**
- 2 DIAGNOSTIC RELEVANCE**
- 3 TEST PRINCIPLE SERION ELISA *classic***
- 4 KIT COMPONENTS**
- 5 MATERIAL REQUIRED BUT NOT SUPPLIED**
- 6 STORAGE AND STABILITY**
- 7 TEST PROCEDURE SERION ELISA *classic***
 - 7.1 General information
 - 7.2 Sample Preparation and Storage
 - 7.3 Preparation of Kit Reagents
 - 7.4 Overview - Test Procedure
 - 7.5 Manual Test Procedure
 - 7.6 Automated Test Procedure
- 8 TEST EVALUATION**
 - 8.1 SERION ELISA *classic*
 - 8.2 Automated Evaluation / Software
 - 8.3 Borderline Ranges
 - 8.4 Limits of Quantification
 - 8.5 Qualitative Evaluation with SERION ELISA *classic*
 - 8.6 Criteria of Validity
 - 8.7 Interpretation of Results
 - 8.8 Reference Range of Healthy Individuals
- 9 PERFORMANCE CHARACTERISTICS**
 - 9.1 Sensitivity and Specificity
 - 9.2 Reproducibility
 - 9.3 Cross-reactivities
 - 9.4 Interfering substances
- 10 SAFETY MEASURES**
 - 10.1 Statements of Warning
 - 10.2 Disposal
 - 10.3 Limitation of the test
- 11 LITERATUR / REFERENCES / RÉFÉRENCES / BIBLIOGRAFIA / BIBLIOGRAFÍA / REFERÊNCIAS / ΑΝΑΦΟΡΕΣ / ΟΔΚΑΖΥ / BIBLIOGRAFIA / ЛИТЕРАТУРА / REFERENCER / REFERENSER / REFERENCIE / REFERENCE / REFERANSER / REFERENCIÁK**

SERION ELISA *classic* Francisella tularensis IgG/IgM

Enzyme-immunoassay for determination of human antibodies for *in vitro* diagnostic use

SERION ELISA *classic* Francisella tularensis IgG

Order Nr.: ESR142G

SERION ELISA *classic* Francisella tularensis IgM

Order Nr.: ESR142M

1 INTENDED USE

The SERION ELISA *classic* Francisella tularensis IgG and IgM tests are qualitative and quantitative immunoassays for the detection of human antibodies in serum or plasma directed against the lipopolysaccharide (LPS) of *Francisella tularensis*. The assays are recommended for the diagnosis of tularemia, to monitor the success of vaccination, to determine the immune status as well as for epidemiological studies.

2 DIAGNOSTIC RELEVANCE

Tularemia is a zoonosis caused by the *Francisella tularensis* bacterium and which can manifest in a variety of clinical conditions. Since the condition in animals resembles that of plague and the disease often affects hares and wild rabbits, it is also called rodent plague. Other traditional names for it are rabbit fever, lemming fever or Parinaud's disease.

Francisella tularensis (formerly also called *Pasteurella tularensis*) is a gram-negative pleomorphic bacterium. The three clinically relevant forms of the four subspecies are difficult to differentiate serologically. Two types can be distinguished epidemiologically, biochemically and genotypically: *Francisella tularensis* biovar *tularensis* (type A) is highly virulent and, untreated, the infection has a high mortality rate. *Francisella tularensis* biovar *holarctica* (type B) is much less virulent but can also cause severe illness.

Various small mammals, such as hares, rabbits, mice, rats and squirrels, are natural reservoirs of *Francisella tularensis*. The pathogen has also been detected in soil samples and water courses and can survive there for a prolonged period depending on climatic conditions. Human infection can occur through direct skin and mucosal contact with infected animals or their excreta. Ectoparasites can also be considered as vectors. Consumption of infected and insufficiently cooked meat and inhalation of infectious dust are also potential routes of infection. Transmission from human to human is not likely and is hitherto unknown.

Tularemia occurs throughout the northern hemisphere between 30 and 71 degrees of latitude, especially in Scandinavia, Russia, Japan, China, USA and Canada. The rural population is often affected. In Germany, tularemia is regarded as a rather rare infectious disease.

The first symptoms of tularemia usually appear two to five days after infection has occurred. However, depending on the dose of infection, the route of infection and the virulence of the bacterial strain, the incubation period can be between one and 21 days. Besides the classical general symptoms such as fever, malaise and joint and muscle pains, the clinical picture of tularemia can be very varied. The following forms are distinguished clinically:

- Ulceroglandular: Skin ulcers with regional lymph node swelling (LNS)
- Glandular: Regional LNS without skin ulcers
- Oculoglandular: Conjunctivitis with swelling of periauricular lymph nodes
- Oropharyngeal: Stomatitis, pharyngitis, tonsillitis, swelling of the cervical lymph nodes
- Intestinal: Abdominal pain, diarrhoea and vomiting
- Pulmonary: Primary disease of the lungs and pleura
- Typhoidal: Primary febrile disease with sepsis

Inhalation of the pathogen often leads to pulmonary manifestation (e.g. pneumonia) or to a septic, typhus-like illness. Infection through the digestive tract can lead to vomiting, abdominal pain and diarrhoea.

When identified promptly, tularemia can be treated effectively with antibiotics. The failure of many organ systems and involvement of the central nervous system lead to death in 40 % of cases of infection with the type A bacteria if untreated; with treatment, the mortality is about 1 %. Infection with type B bacteria has a mild course with low mortality with all routes of infection.

3 TEST PRINCIPLE SERION ELISA *classic*

The ELISA (Enzyme Linked Immunosorbent Assay) is an immunoassay, which is particularly suited to the determination of antibodies in the field of infectious serology. The reaction is based on the specific interaction of antibodies with their corresponding antigen. The test strips of the SERION ELISA *classic* microtiter plate are coated with specific antigens of the pathogen of interest. If antibodies in the patient's serum sample are present, they bind to the fixed antigen. A secondary antibody, which has been conjugated with the enzyme alkaline phosphatase, detects and binds to the immune complex. The colourless substrate p-nitrophenylphosphate is then converted into the coloured product p-nitrophenol. The signal intensity of this reaction product is proportional to the concentration of the analyte in the sample and is measured photometrically.

4 KIT COMPONENTS

Test Components	Pieces / Volume
Break apart microtiter test strips each with eight antigen coated single wells, (altogether 96) [MTP] , 1 frame. The coating material is inactivated.	12 pieces
Standard serum (ready-to-use) [STD] , Human serum in protein containing phosphate buffer; negative for anti-HIV Ab, HBs-Ag (Hepatitis B-Virus surface antigen) and anti-HCV Ab; preservative: < 0.1 % sodium azide; colouring: Amaranth O	2 x 2 ml
Negative control serum (ready-to-use) [NEG] , Human serum in protein containing phosphate buffer; negative for anti-HIV Ab, HBs-Ag (Hepatitis B-Virus surface antigen) and anti-HCV Ab; preservative: < 0.1 % sodium azide; colouring: Lissamin Green V	2 ml
Anti-human IgA, IgG or IgM conjugate (ready-to-use) [APC] , Anti-human IgA, IgG or IgM polyclonal antibody, conjugated to alkaline phosphatase, stabilised with protein stabilisation solution; preservative: < 0.1 % methylisothiazolone, < 0.1 % bromnitrodioxane	13 ml
Washing solution concentrate (sufficient for 1000 ml) [WASH] , Sodium chloride solution with Tween 20 and 30 mM Tris/HCl, pH 7.4; preservative: < 0.1 % sodium azide	33.3 ml
Dilution buffer (ready-to-use) [DILB] , Protein containing phosphate buffer with Tween 20; preservative: < 0.1 % sodium azide; colouring: 0.01 g/l Bromphenol blue	2 x 50 ml
Stopping solution (ready-to-use) [STOP] , < 0.1 N sodium hydroxide, 40 mM EDTA	15 ml
Substrate (ready-to-use) [pNPP] , Para-nitrophenylphosphate in solvent free buffer; preservative: < 0.1 % sodium azide	13 ml
Quality control certificate with standard curve and evaluation table [INFO] , (quantification of antibodies in IU/ml or U/ml)	2 pages

5 MATERIAL REQUIRED BUT NOT SUPPLIED

- Common laboratory equipment
- For the IgM detection: SERION Rf-Absorbent (Order Nr. Z200 (20 ml))
- Photometer for microtiter plates with filter, wavelength 405 nm, recommended reference wavelength 620 nm - 690 nm (e.g. 650 nm)
- Microtiter plate washer
- Incubator 37 °C
- Moist chamber
- Distilled water
- Click-Clips (Order Nr. VT120.1)
- Optional: SERION ELISA *control*

6 STORAGE AND STABILITY

Reagent	Storage	Stability
Microtiter strips (coated with antigen)	unopened after opening at 2 – 8 °C in closed aluminum bag with desiccant	see expiry date 6 months
Control sera / Standard sera	unopened after opening at 2 – 8 °C	see expiry date 6 months
Conjugate	unopened after opening at 2 – 8 °C	see expiry date 6 months
Dilution buffer	unopened after opening at 2 – 8 °C	see expiry date 6 months
Washing solution	unopened / after opening at 2 – 8 °C working dilution at 2 – 8 °C working dilution at room temperature	see expiry date 2 weeks 1 week
Substrate	unopened after opening at 2 – 8 °C	see expiry date 6 months
Stopping solution	unopened after opening at 2 – 8 °C	see expiry date 6 months

7 TEST PROCEDURE SERION ELISA *classic*

7.1 General information

Optimum results can only be achieved if the instructions are strictly followed. Only use SERION ELISA *classic* reagents when using SERION ELISA *classic* immunoassays. The components must not be exchanged for reagents of other manufacturers. Standard and control sera of SERION ELISA *classic* immunoassays are defined exclusively for the test kit to be used and must not be used in other lots. Washing solution, substrate and stop solution can be used for all SERION ELISA *classic* immunoassays irrespective of the lot and the test.

Each SERION ELISA *classic* test contains a ready-to-use sample dilution buffer. In some cases the use of special dilution buffers is necessary to guarantee consistent quality and reliable results. The dilution buffers can be used irrespective of the lots.

There are three different conjugate concentrations for each immunoglobulin class (IgA, IgG, IgM), indicated on the label as + (low), ++ (medium) and +++ (high). Conjugates with the same concentration and of the same immunoglobulin class are interchangeable and can be used for other SERION ELISA *classic* immunoassays irrespective of the lot and the test. Dilution or alteration of the reagents may result in a loss of sensitivity. Use aseptic techniques when removing aliquots from the reagent tubes to avoid contamination.

Reproducibility of test results is dependent on thorough mixing of the reagents. Agitate the flasks containing control sera before use and also all samples after dilution (e.g. by using a vortex mixer).

Be sure to pipette carefully and comply with the given incubation times and temperatures. Significant time differences between pipetting the first and last well of the microtiter plate when dispensing samples and control sera, conjugate or substrate can result in different pre-incubation times, which may influence the precision and reproducibility of the results. Avoid exposure of reagents to strong light during storage and incubation.

Adequate washing avoids test unspecificities. Therefore, the washing procedure should be carried out carefully. All of the flat bottom wells should be filled with equal volumes of washing buffer. At the end of the procedure ensure that the wells are free of all washing buffer in order to avoid uncontrolled dilution effects. Avoid foaming!

Reagents must be tightly closed after use to avoid evaporation and contamination. Take care not to mix-up the caps of the bottles and/or vials.

The SERION ELISA *classic* immunoassay is only valid if the lot-specific validation criteria on the quality control certificate are fulfilled.

7.2 Sample Preparation and Storage

Lipaemic, hemolytic or icteric samples (serum or plasma) should only be tested with caution. Obviously contaminated samples should not be tested. Serum or plasma (EDTA, citrate, heparin) collected according to standard laboratory methods are suitable samples. Samples must not be thermally inactivated.

7.2.1 Dilution of Samples

Before running the test, patient samples (V_1) must be diluted in dilution buffer (V_2) as follows:

SERION ELISA *classic* Francisella tularensis IgG

$V_1 + V_2 = 1+100$	add	10 μ l	patient's sample
	to each	1000 μ l	dilution buffer

After dilution and before pipetting into the microtiter plate the samples must be mixed thoroughly to prepare a homogenous solution.

SERION ELISA classic *Francisella tularensis* IgM

Interference with rheumatoid factors

Rheumatoid factors are autoantibodies mainly of the IgM class, which preferably bind to IgG immune complexes. The presence of non-specific IgM antibodies (rheumatoid factors) can lead to false-positive results in the IgM assay. Furthermore, the possibility exists, that weak-binding pathogen-specific IgM antibodies may be displaced by stronger-binding IgG antibodies leading to a false-negative IgM result. Therefore it is necessary to pretreat samples with rheumatoid factor-absorbents prior to IgM detection (SERION Rf-Absorbent, Order Nr.: Z200 (20 ml/100 tests)). Rf-absorption is performed by incubation of the patient's sample in Rf-dilution buffer for 15 minutes at room temperature or over night at 4 °C. The test procedure is described in a separate instruction manual.

Before running the test, rheumatoid factor-absorbent (V₁) must be diluted 1+4 in dilution buffer (V₂).

V ₁ + V ₂ = V ₃ (1+4)	add	200 µl	Rf absorbent
	to each	800 µl	dilution buffer

Patient's samples (V₄) must be diluted in this Rf-dilution buffer (V₃):

V ₄ + V ₃ = 1 +100	add	10 µl	patient's sample
	to each	1000 µl	Rf-dilution buffer

After dilution and before pipetting into the microtiter plate the samples must be mixed thoroughly to prepare a homogenous solution.

7.2.2 Sample Storage

The patient's samples should not be stored for more than 7 days at 2 – 8 °C. Extended storage is possible at ≤ -20 °C. Avoid repeated freezing and thawing of samples. Diluted samples can be stored at 2 – 8 °C for one week.

7.3 Preparation of Kit Reagents

Bring all reagents to room temperature before testing.

7.3.1 Microtiter Test Strips

The microtiter test strips labeled with abbreviations for pathogen and immunoglobulin class are packed with a desiccant in an aluminum bag. To open the aluminum bag of the microtiter plate please cut off the top of the marked side only, in order to guarantee proper resealing. Take unrequired cavities out of the frame and put them back into the aluminum bag. Close bag carefully to ensure airtight conditions. Do not use the strips if the aluminum bag is damaged or if the bag with remaining strips and desiccant was not properly resealed.

7.3.2 Negative control Sera / Standard Sera (ready-to-use)

Negative control and standard sera are ready-to-use and must not be diluted any further. For each test run - independent of the number of microtiter test strips to be used – negative control and standard sera must be included. Standard sera should be set up in duplicate. Do not treat negative control and standard sera with Rf-absorbent.

7.3.3 Anti-human IgA, IgG or IgM AP-Conjugate (ready-to-use)

The required conjugate concentration (+, ++, +++) is indicated on the quality control certificate. Please refer also to the specification on the label. Avoid contamination.

7.3.4 Washing Solution (Concentrate)

Dilute washing buffer concentrate (V_1) 1:30 with aqua dest. to a final volume of V_2 . Bottles used for the working dilution should be cleaned regularly. Discard cloudy solutions.

Example:

Buffer concentrate (V_1)	Final volume (V_2)
33.3 ml	1000 ml
1.0 ml	30 ml

7.3.5 Dilution Buffer for Samples (ready-to-use)

Discard cloudy solutions.

7.3.6 Substrate (ready-to-use)

Substrate in unopened bottle may have a slightly yellow coloring, which does not reduce the quality of the product! Avoid contamination.

7.3.7 Stopping Solution (ready-to-use)

7.4 Overview - Test Procedure

SERION ELISA *classic* Francisella tularensis IgG / IgM quantitative

In case of IgM detection absorption of rheumatoid factor, see No. 7.2.1;
Incubation 15 minutes at room temperature or over night at 4°C

sample dilution¹
(patient's samples)
1+100

Pipette diluted samples and ready-to-use negative control /
standard sera into the microtest wells (100 µl)



INCUBATION 60 min./ 37 °C
moist chamber



WASH (4 x 300 µl **DIL** **WASH**)²



Pipette conjugate solution **APC** (100 µl)



INCUBATION 30 min./ 37 °C
moist chamber



WASH (4 x 300 µl **DIL** **WASH**)²



Pipette substrate solution **pNPP** (100 µl)



INCUBATION 30 min./ 37 °C
moist chamber / dark incubation



Pipette stopping solution **STOP** (100 µl)



READ EXTINCTION at 405 nm

¹Special dilution buffers for the following SERION ELISA *classic* tests:
Borrelia burgdorferi IgG, IgM and EBV EA IgG.

²For manual use:
tap plate at the end of the wash procedure on paper towel.

7.5 Manual Test Procedure

1. Place the required number of **cavities in the frame** and prepare a protocol sheet.
2. Add each **100 µl of diluted sample or ready-to-use negative control/standard sera** into the appropriate wells of microtiter test strips. Spare one well for substrate blank, e.g.:

Well	Quantitative ELISA
A1	substrate blank
B1	negative control
C1	standard serum
D1	standard serum
E1	patient 1 ...
F1	patient 2 ...

3. **Sample incubation** for 60 minutes (+/- 5 min.) at 37 °C (+/- 1°C) in moist chamber
4. After incubation **wash** all wells with washing solution (by automated washer or manually):
 - aspirate or shake out the incubation solution
 - fill each well with 300 µl washing solution
 - aspirate or shake out the washing buffer
 - repeat the washing procedure 3 times (altogether 4 times!)
 - dry by tapping the microtiter plate on a paper towel
5. **Addition of conjugate**
Add 100 µl of the ready-to-use IgG/IgM conjugate to the appropriate wells (except substrate blank)
6. **Conjugate incubation** for 30 minutes (+/- 1 min.) at 37 °C (+/- 1 °C) in moist chamber.
7. After incubation **wash** all wells with washing solution (see above).
8. **Addition of substrate**
Add 100 µl of ready-to-use substrate solution to each well (including well for substrate blank!)
9. **Substrate incubation** for 30 minutes (+/- 1 min.) at 37 °C (+/- 1 °C) in moist chamber. Ensure dark incubation.
10. **Stopping of the reaction**
Add 100 µl stopping solution to each well, shake microtiter plate gently to mix.
11. **Read extinction**
Read optical density (OD) within 60 minutes at 405 nm against substrate blank, reference wave length between 620 nm and 690 nm (e.g. 650 nm).

7.6 Automated Test Procedure

SERION ELISA are validated for use with Immunomat (using the following consumables: VT124, VT111, VT112) and suited for processing on similar analyzers. For processing on the Immunomat the current software version including reagent check has to be used. The automated processing is performed analogous to manual use. Please note, that under special working-conditions internal laboratory adaptations of the substrate incubation times may be necessary.

8 TEST EVALUATION

8.1 SERION ELISA *classic* Francisella tularensis IgG/IgM

The mathematical curve fitting for antibody quantification with SERION ELISA *classic* immunoassays is based on the 4-parameter logistic (4 PL) function.

$$Activity (U / ml) = e^{C - \frac{1}{B} \ln\left(\frac{D-A}{OD(Patient)*F-A}\right)^{-1}}$$

The 4 parameters A, B, C, and D are representative for the exact shape of the standard curve:

Parameter A:	Lower asymptote (OD)
Parameter B:	Slope of the curve
Parameter C:	Inflection point
Parameter D:	Upper asymptote (OD)

Institut Virion\Serion GmbH establishes a lot-specific 4 PL standard curve for each SERION ELISA *classic* immunoassay in multiple test runs under optimal test conditions. The four parameters are indicated on the quality control certificate of each individual SERION ELISA *classic* test.

For the adaption of the test level to the given 4 PL standard curve the correction factor F is calculated by dividing the standard reference OD value indicated on the quality control certificate with the measured, and consequently test run-specific, standard OD value.

$$F = \frac{STD \text{ reference OD value}}{\text{measured STD OD value}}$$

By multiplying the OD values obtained from patient samples with the correction factor F, the level of each individual test run is adjusted to the given 4 PL standard curve. Thereby, interassay deviations are compensated for and antibody activities can be directly evaluated from the 4 PL standard curve.

After subtraction of the substrate blank from all measured OD values and calculation of the mean OD value of the standard serum (STD), tested in duplicate, the evaluation of antibody activities from the optical measurement signals (OD) of patient samples can be performed with the 4PL function presented above.

8.2 Automated Evaluation / Software

For the automated evaluation of optical measurement signals, the Software SERION easyANALYZE as well as the Microsoft® Excel®-based software tool SERION activity are available on request.

8.3 Borderline Ranges

The borderline ranges of the SERION ELISA *classic* Francisella tularensis IgG/IgM tests are specified on the quality control certificates and indicate the range of borderline test results. Values below this range indicate a negative test result; values above the borderline range are interpreted positive.

8.4 Limits of Quantification

The limits of quantification are specified on the quality control certificate of the SERION ELISA *classic* Francisella tularensis IgG/IgM. The linearity of dilution within this range has been demonstrated in comprehensive evaluation studies. In case a patient sample shows a test result above the upper limit of quantification, the sample may be tested at a higher dilution. The resulting antibody activity must then be multiplied by the additional dilution factor.

8.5 Qualitative Evaluation with SERION ELISA *classic* Francisella tularensis IgG/IgM

For the SERION ELISA *classic* test evaluation a lot-specific quality control certificate with standard curve and an evaluation table is included in the test kit so that the obtained OD values may be assigned to the corresponding antibody activities. The substrate blank must be subtracted from all OD values prior to evaluation. Mean OD value of the standard serum (STD), tested in duplicate, has to be used.

Method 1:

In the first line of the table, several ranges of OD values for the standard serum are depicted covering the whole standard validity range. According to the measured mean OD value of the standard serum, the corresponding column can be chosen. This column contains the information of upper and lower cut-off OD values to allow evaluation of the patient sample. OD values below the lower cut-off are evaluated negative and values above the upper cut-off are evaluated positive. Implementation of the correction factor F is not necessary in the context of the evaluation table.

Method 2:

Qualitative Evaluation

To fix the cut-off ranges multiply the mean value of the measured standard OD with the numerical data of the quality control certificate (see special case formulas), e.g.:

OD = 0.502 x MW(STD) with upper cut-off

OD = 0.352 x MW(STD) with lower cut-off

If the measured mean absorbance value of the standard serum is 0.64 OD, the range of the cut-off is in between 0.225-0.321 OD.

Calculation example:

Standard serum mean OD = 0.64

Upper cut-off: OD = 0.502 x 0.64 = 0.321

Lower cut-off: OD = 0.352 x 0.64 = 0.225

8.6 Criteria of Validity

The substrate blank must be < 0.25 OD.

The negative control must be negative.

The mean OD value (after subtraction of the substrate blank!) of the standard serum must be within the validity range, which is given on the lot specific quality control certificate.

The variation of OD values of the standard serum must not be higher than 20 %.

If these criteria are not met, the test is not valid and must be repeated.

8.7 Interpretation of Results

A positive test result confirms the presence of specific antibodies. A negative result indicates that no clinically relevant antibodies against the pathogen are present in the patient's sample, but does not exclude the possibility of an acute infection. In case of a borderline result a reliable evaluation is not possible. A definitive diagnosis can only be achieved by testing paired serum samples, taken at one to two weeks intervals, in parallel.

A negative result in the SERION ELISA *classic* Francisella tularensis indicates that there are no antibodies in the serum to the lipopolysaccharide of the pathogen. In the case of a borderline result, the test should be repeated in parallel with a new sample taken after an interval of one to two weeks (paired sera). A positive result confirms the presence of LPS-specific antibodies.

Generally, the immune status is verified four to eight weeks after basic vaccination is completed. Positive results confirm immunity; however the duration of effective immunity cannot be inferred from the antibody concentration measured.

Possible cross-reactivity with related genera, e.g. *Brucella* or *Yersinia* cannot be ruled out. Because of its clinical manifestations, tularemia can easily be mistaken for a range of similar diseases. These include lymphadenitis in association with streptococcal and staphylococcal infections, bubonic plague, brucellosis, cat-scratch disease, sporotrichosis and *Pasteurella multocida* infections and also mumps. The septicaemic and intestinal forms should be distinguished from typhus, pseudotuberculosis, actinomycosis, lymphogranulomatosis or infectious mononucleosis. Granulomatous changes in the lungs, like most of the other symptoms of tularemia, can easily raise the suspicion of tuberculosis. With the corresponding clinical picture and negative tests for mycobacteria, tularaemia should always be considered in the differential diagnosis. The pulmonary forms must also be distinguished from abscess-forming pneumonias, pneumonic plague, mycoplasma pneumonia, Q fever, melioidosis, glanders and pulmonary mycoses.

8.8 Reference Range of Healthy Individuals

Testing of random blood donor sera, collected in the region of southern Germany, with SERION ELISA *classic* Francisella tularensis resulted in the following distribution:

SERION ELISA <i>classic</i>	Number	negative	borderline	positive
Francisella tularensis IgG	105	101 (96.2 %)	2 (1.9 %)	2 (1.9 %)
Francisella tularensis IgM	105	104 (99.0 %)	-	1 (1.0 %)

9 PERFORMANCE CHARACTERISTICS

9.1 Sensitivity and Specificity

The evaluation of SERION ELISA *classic* Francisella tularensis IgG was performed in an internal study with 98 serum samples of healthy blood donors, 50 sera from patients with acute infection and 7 sera with reaction patterns of infection in the past against the ELISA of another manufacturer. The evaluation of SERION ELISA *classic* Francisella tularensis IgM was performed in an internal study with 97 serum samples of healthy blood donors and 55 from patients with infections against the ELISA of another manufacturer. Borderline results were not included in the calculation of sensitivity and specificity.

	Sensitivity	Specificity
SERION ELISA <i>classic</i> Francisella tularensis IgG	> 99 %	99.0 %
SERION ELISA <i>classic</i> Francisella tularensis IgM	> 99 %	96.4 %

9.2 Reproducibility

SERION ELISA *classic* Francisella tularensis IgG:

Sample	Mean Value (OD)	Intraassay CV (%)	Mean Value (OD)	Interassay CV (%)
Serum 1	0.810	3.4	0.859	6.3
Serum 2	1.153	2.1	1.239	8.4
Serum 3	1.898	2.7	2.007	3.6

SERION ELISA *classic* Francisella tularensis IgM:

Sample	Mean Value (OD)	Intraassay CV (%)	Mean Value (OD)	Interassay CV (%)
Serum 1	0.445	7.4	0.574	8.2
Serum 2	0.604	5.9	0.607	9.2
Serum 3	1.307	4.4	1.219	7.9

9.3 Cross-reactivities

SERION ELISA *classic* Francisella tularensis IgG

To determine detection of cross-reactive antibodies directed against different parameters sera were analyzed with SERION ELISA *classic* Francisella tularensis IgG and a commercially available anti-Francisella tularensis ELISA. Positive sera (10 sera each) for Yersinia IgG, Cytomegalovirus IgG, Toxoplasma gondii IgG and Epstein-Barr Virus VCA IgG have been tested as well as sera positive for rheumatoid factor (RF) and anti-nuclear antibodies (ANA). Within this internal evaluation potential cross-reactivities with one ANA positive serum has been observed. All reactivities have been confirmed by positive or borderline results in the reference assay. Other cross-reactivities cannot be ruled out in general.

SERION ELISA *classic* Francisella tularensis IgM

To determine detection of cross-reactive antibodies directed against different parameters sera were analyzed with SERION ELISA *classic* Francisella tularensis IgM and a commercially available anti-Francisella tularensis ELISA. Positive sera (10 sera each) for Yersinia IgM, Cytomegalovirus IgM, Toxoplasma gondii IgM and Epstein-Barr Virus VCA IgM have been tested as well as sera positive for rheumatoid factor (RF) and anti-nuclear antibodies (ANA). Within this internal evaluation no potential cross-reactivities have been observed. Other cross-reactivities cannot be ruled out in general.

9.4 Interfering substances

SERION ELISA *classic* Francisella tularensis IgG/IgM

To determine the influence of interfering substances, sera with different reactivities were analyzed with SERION ELISA *classic* Francisella tularensis IgG/IgM. No interferences have been detected for sera with concentrations up to 2.00 g/L hemoglobin, 11.50 g/L lipemia/triglyceride or 0.201 g/L bilirubin (conjugated and unconjugated).

10 SAFETY MEASURES

10.1 Statements of Warning

The SERION ELISA *classic* is designed for use by qualified personnel who are familiar with good laboratory practice. All kit reagents and human specimens should be handled carefully, using established good laboratory practice.

- This kit contains human blood components. Although all control- and cut-off sera have been tested and found negative for anti-HIV-ab, HBs-Ag (*Hepatitis B-Virus-surface Antigen*) and anti-HCV-ab, they should be considered potentially infectious.
- Do not pipette by mouth.
- Do not smoke, eat or drink in areas in which specimens or kit reagents are handled.
- Wear disposable gloves, laboratory coat and safety glasses while handling kit reagents or specimens. Wash hands thoroughly afterwards.
- Patient's material and other potentially infectious material should be decontaminated after the test run.
- Reagents should be stored safely and be inaccessible to unauthorized access e.g. children.

10.2 Disposal

Please observe the relevant statutory requirements!

10.3 Limitation of the test

Please note that diagnosis should never be solely based on serological data. Rather, serological results have to be interpreted in the context of the clinical picture and other diagnostic findings.

11 LITERATUR / REFERENCES / RÉFÉRENCES / BIBLIOGRAFIA / BIBLIOGRAFÍA / REFERÊNCIAS / ΑΝΑΦΟΡΕΣ / ODKAZY / BIBLIOGRAFIA / ЛИТЕРАТУРА / REFERENCER / REFERENSER / REFERENCIE / REFERENCE / REFERANSER / REFERENCIÁK

- [1] Ellis, J., Oyston, P.C.F., Green, M., Titball, R.W. (2002) Tularemia. Clin. Microbiol. Rev. 15, 631 – 46.
- [2] Fritzsche, J., Splettstoesser, WD. (2010) Septic pneumonic tularaemia caused by Francisella tularensis subsp. holarctica biovar II. J. Med. Microbiol. 59, 1123 – 5.
- [3] Grunow, R., Splettstößer, W., Hirsch, F.W., Kleemann, D., Finke, E.-J. (2001) Differentialdiagnose der Tularämie. Dtsch. Med. Wschr. 126, 408 – 13.
- [4] Haristoy, X., Lozniewski, A., Tram, C., Simeon, D., Bevanger, L., Lion, C. (2003) Case Reports Francisella tularensis bacteremia. J. Clin. Microbiol. 41, 2774 – 6.
- [5] Svensson, K., Larsson, P., Johansson, D., Byström, M., Forsman, M., Johansson, A. (2005) Evolution of subspecies of Francisella tularensis. J. Bacteriol. 187, 3903 - 8.
- [6] Yeşilyurt, M., Kiliç, S., Çelebi, B., Gül, S. (2013) Tularemia during pregnancy: Report of four cases. Scand. J. Infect. Dis. 45, 324 – 8.

SERION ELISA classic

(V 18/04-1)

Symbole auf den Etiketten/ symbols on labels/ symboles et étiquettes/ simboli sulle etichette/ символы на этикетках/símbolos sobre las etiquetas/ σύμβολα στις ετικέτες/ símbolos nos rótulos / Symboly na štítcích / symboler på etiketter/ symboler på etiketterna/ Symbole na etykietach/ symboly na označení/ Simboli na oznakah/ symbol på etiketter



Hersteller/ Manufacturer/ Fabricant/ Produttore/Производитель/ Fabricante/ Κατασκευαστής/ Fabricante/ Výrobce/ Fremstiller/ Tillverkare/ Producent/ Výrobca/ Izdelovalec/ Producent



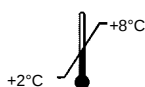
Ausreichend für 96 Tests/ sufficient for 96 tests/ suffisant pour 96 tests/ sufficiente per 96 test/ достаточно для 96 тестов / suficiente para 96 pruebas/ επαρκεί για 96 δοκιμασίες/ suficiente para 96 ensaios/ stačí na 96 testů/ nok til 96 test/ tillräckligt för 96 tester/ Wystarcza na 96 testów/ postačuje na 96 testov/ Zadostuje za 96 testov/ Tilstrekkelig til 96 tester



Charge/ lot/ lot / lotto/ lote/ παρτίδα/ lote/ šarže/ lot/ lot/ seria/ šarža/ serija/ lot /lot



Referenz oder Bestellnummer/ reference or order number/ numéro de référence ou de commande/ numero di riferimento o ordinazione/ ссылка или номер для заказа / referencia o número de pedido/ Αριθμός αναφοράς ή παραγγελίας/ referência ou número para encomenda/ reference nebo číslo objednávky/ reference eller bestillingsnummer/ referens eller beställningsnummer/ Numer referencyjny lub numer zamówienia/ referenčné číslo alebo číslo objednávky/ referenčna ali kataloška številka/ Referanse eller ordrenummer

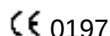


Lagern zwischen 2 und 8 Grad Celsius/ store between 2 and 8 degree celsius/ entre 2 et 8 degré celsius/ conservare a temperatura compresa tra 2 e 8 gradi centigradi/ хранить при температуре от 2 до 8 градусов цельсия / conservar entre 2 y 8 grados celsius/ Φύλαξη μεταξύ 2 και 8 βαθμούς Κελσίου/ Armazenar entre 2º e 8º Celsius/ uchovávejte při teplotě 2 až 8 °C/ opbevares mellem 2 og 8 grader celsius/ förvara vid 2 till 8 grader Celsius/ Przechowywać w temp. pomiędzy 2

a 8 stopni Celsjusza/ skladovať pri teplote 2 až 8 stupňov Celzia/ Shranjujte pri temperaturi od 2 do 8 C/ Oppbevares mellom 2 og 8 grader Celsiu



CE-Markierung bei Erfüllung der IVD Richtlinie 98/79 EG/ CE marking according to IVD guideline 98/79 EC/ Étiquetage CE selon les directives DIV/ marcatura CE in conformità alla direttiva IVD 98/79 EC/ маркировка CE согласно директивам IVD 98/79 /marca CE según la directiva IVD 98/79 CE/ Σήμανση CE σύμφωνα με την οδηγία IVD 98/79 EE/ Marcação CE de acordo com a Directiva 98/79/ značení CE podle směrnice IVD 98/79/ES/ CE-mærkning iht. IVD-retningslinje 98/79/EF/ CE-märkning enligt riktlinjerna för IVD i direktiv 98/79/EC/ Oznakowanie CE zgodne z wytycznymi dot. diagnostyki in vitro 98/79 EC/ označenie CE podľa smernice IVD 98/79/ES/ oznaka CE, skladna s smernico IVD 98/79/ES/ CE-merking i henhold til IVD-retningslinjer 98/79/EØF



CE-Markierung bei Erfüllung der IVD Richtlinie 98/79 EG gemäß Anhang II, Liste B/ CE marking according to IVD guideline 98/79 EC according to annex II, list B/ Étiquetage CE selon les directives DIV 98/79 CE selon l'annexe II, liste B/ marcatura CE in conformità alla direttiva IVD 98/79 EC secondo l'allegato II, elenco B/ маркировка CE согласно директивам IVD 98/79, приложение II, список B / marca CE según la directiva IVD 98/79 CE de acuerdo con el anexo II, lista B/ Σήμανση CE σύμφωνα με την οδηγία IVD 98/79 EE, σύμφωνα με το παράρτημα II, κατάλογο B/ Marcação CE de acordo com a Directiva 98/79/ CE relativo aos dispositivos médicos de diagnóstico *in vitro*, segundo a lista B do anexo II/ značení CE podle směrnice IVD 98/79/ ES podle příloh II, seznamu B/ CE-mærkning iht. IVD-retningslinje 98/79 /EF iflg. annekks II, liste B/ CE-märkning enligt riktlinjerna för IVD i direktiv 98/79/EC, bilaga II, lista B/ Oznakowanie CE zgodne z wytycznymi dot. diagnostyki in vitro 98/79 EC, zgodnie z aneksem II, lista B/ označenie CE podľa smernice IVD 98/79 ES v znení dodatku II, zoznam B/ oznaka CE, skladna s smernico IVD 98/79/ES in seznamom B v Dodatku II/ CE-merking i henhold til IVD-retningslinjer 98/79/EØF, tillegg II, liste B



Verfallsdatum/ expiry date/ date d'expiration/ data di scadenza/ срок годности до /fecha de caducidad/ ημερομηνία λήξης/ data de validade/ datum expirace/ udløbsdato/ förfallodatum/ data upływu ważności/ dátum expirácie/ datum izteka roka uporabnosti/ utløpsdatp



Mikrotiterplatte (brechbare Streifen)/ microtiter plate (breakable strips)/ plaque de microtitration (bandelettes détachables)/ piastra per microtitolazione (strisce separabili)/ микротитровальная панель (отрывные стрипы) /placa de microtitulación (tiras rompibles)/ Πλάκα μικροτιτλοποίησης (αποσπώμενες ταινίες)/ placa de microtitulação (tiras quebráveis)/ mikrotitrační deska (rozlomitelné proužky)/ mikrotiterplade (afbrækkelige strimler)/ mikrotiterplatta (brytbara strips)/ Płytką mikrotitracyjną (paski do odrywania)/ mikrotitračná platnička (rozlomitelné pružky)/ vsebnik za mikrotitriranje (z razdelki, ki jih je mogoče odlomiti)/ Mikrotiterplate (avbrytbare strips)



Antigen/ antigen/ Antigène/ antigene/ антиген /antígeno/ αντιγόνο/ antigénio/ antigen/ antigen/ antigen/ Antygen/ antigén/ antigen/ Antigen



Antikörper/ antibodies/ Anticorps/ anticorpi/ антитела / anticuerpos/ αντίσωμα/ anticorpos/ protilátky/ antistoffer/ antikroppar/ Przeciwciała/ protilátky/ protitelesa/ Antistoffer



Kontrollantigen/ control antigen/ antigène de contrôle/ antigene di controllo/ контрольный антиген /antígeno de control/ αντιγόνο ελέγχου/ antígeno de controle/ kontrolní antigen/ kontrolantigen/ kontrollantigen/ antygen kontrolny/ kontrolný antigén/ kontrolni antigen/ kontrollantigen



Standardserum/ standard serum/ Sérum standard/ siero standard/ стандартная сыворотка /suero patrón/ πρότυπος ορός/ soro padrão/ standardní sérum/ standardserum/ standardserum/ Surowica standardowa/ štandardné sérum/ standardni serum/ Standardserum



Positivkontrolle/ positive control/ Contrôle positif/ controllo positivo/ положительные контроли /control positivo/ θετικός έλεγχος/ controlo positivo/ pozitivní kontrola/ positiv kontrol/ positiv kontroll/ Kontrola pozytywna/ pozitívna kontrola/ pozitivna kontrola/ Positiv kontroll



Grenzwertiges Serum/ cut-off serum/ Sérum seuil/ siero cut-off/ сомнительные сыворотки (пограничные)/suero de corte/ οριακός ορός (cut-off)/ soro *cut-off*/ cut-off sérum/ cutoff-serum/ cutoff-serum/ Surowica „cut-off”/ sérum na určenie hraničnej hodnoty/ mejni serum/ Stoppserum

NEG	Negativkontrolle/ negative control/ Contrôle négatif/ controllo negativo/ отрицательные контроли /control negativo/ αρνητικός έλεγχος/ controllo negativo/ negativní kontrola/ negativ kontroll/ negativ kontroll/ Kontrola negatywna/ negatívna kontrola/ negativna kontrola/ Negativ kontroll
APC	Alkalisches Phosphatase Konjugat antihuman/ alkaline phosphatase conjugate anti-human/ conjugué phosphatase alcaline anti-humain/ coniugato con fosfatasi alcalina anti-umano/ античеловеческий щелочной конъюгат фосфатазы / conjugado anti humano de fosfatasa alcalina/ Σύζευξη αλκαλικής φωσφατάσης/ conjugado anti-humano com fosfatase alcalina/ konjugát alkalické fosfatázy anti-humánní/ alkalisk phosphatase konjugat antihumant/ antihumant alkaliskt fosfatas-konjugat/ Anty-ludzki koniugat fosfatazy alkalicznej/ konjugát antihumánnej alkalickej fosfatázy/ konjugat alkalne fosfataze, antihumani/ Alkalisk fosfatase-konjugat, anti-humant
+	niedrig-konzentriertes Konjugat/ conjugate with low concentration/ conjugué à faible concentration/ coniugato a concentrazione bassa/ конъюгат низкой концентрации /conjugado con concentració baja/ Σύζευξη χαμηλής συγκέντρωσης/ conjugado de baixa concentração/ konjugát s nízkou koncentrací/ konjugat med lav koncentration/ konjugat med låg koncentration/ koniugat o niskim stężeniu/ konjugát so strednou koncentráciou/ konjugat z majhno koncentracijo/ Konjugat med lav konsentrasjon
++	mittel-konzentriertes Konjugat/ conjugate with medium concentration/ conjugué à concentration moyenne/ coniugato a concentrazione media/ конъюгат средней концентрации /conjugado con concentració media/ Σύζευξη μέτριας συγκέντρωσης/ conjugado de concentração intermédia/ konjugát se střední koncentrací/ konjugat med medium koncentration/ konjugat med medelhög koncentration/ koniugat o średnim stężeniu/ konjugát so strednou koncentráciou/ konjugat s srednjo koncent/ Konjugat med middels konsentrasjon
+++	hoch-konzentriertes Konjugat/ conjugate with high concentration/ conjugué à concentration élevée/ coniugato a concentrazione alta/ высококонцентрированный конъюгат/ conjugado con concentració alta/ σύζευξη υψηλής συγκέντρωσης/ conjugado de elevada concentração/ konjugát s vysokou koncentrací/ konjugat med høj koncentration/ konjugat med hög koncentration/ koniugat o wysokim stężeniu/ konjugát s vysokou koncentráciou/ konjugat z veliko koncentracijo/ Konjugat med høy konsentrasjon
RF	Rheumafaktor-Absorbens (Rf-Absorbens)/ rheumatoid factor absorbent (rf-absorbent)/ absorbant de facteur rhumatoïde (rf-absorbant)/ adsorbente del fattore reumatoide (adsorbente Rf)/ абсорбент ревматоидного фактора (Rf-абсорбент) /absorbente de factor reumatoide (material absorbente de Rf)/ Απορροφητής ρευματοειδούς παράγοντα (απορροφητής Rf)/ absorvente de factor reumatóide (absorvente de Fr)/ absorbent revmatoidního faktoru (rf-absorbent)/ reumafaktor-absorptionsmiddel (rf-absorptionsmiddel)/ reumafaktor-absorptionsmedel (rf-absorptionsmedel)/ Absorbent czynnika reumatoidalnego (absorbent RF)/ absorbent reumatoidného faktora (absorbent rf)/ absorbent revmatoidnega faktorja (absorbent RF)/ Revmatoid faktor-absorbent (rf-absorbent)
DILB	Verdünnungspuffer für Serum/ dilution buffer for sera/ sérum pour le tampon de dilution/ tampone di diluizione per sieri / разбавляющий буфер для сыворотки / solución amortiguadora para los sueros/ ρυθμιστικό διάλυμα αραιώσης για ορούς/ tampão de diluição para soro/ ředící pufr pro séra/ fortyndingsbuffer til sera/ spädningsbuffert för serum/ bufor rozcieńczający do surowic / pufor na riedenie sér/ pufer za redčenje seruma/ Fortynningsbuffer til serum
DILBS1	
DILBS2	
WASH	Waschlösungskonzentrat/ washing solution concentrate/ concentré de solution de lavage / soluzione di lavaggio concentrata / промывочный концентрат /concentrado de solución de lavado/ συμπύκνωμα έκπλυσης/ concentrado de solução de lavagem/ koncentrát promývacího roztoku/ vaskeopløsningskoncentrat/ tvättlösningskoncentrat/ Stężony roztwór do płukania/ koncentrát premývacieho roztoku/ koncentrat za raztopino za izpiranje/ Vaskeløsningskoncentrat
pNPP	pNPP Substrat/ pNPP substrate/ substrat Pnpp/ substrato pNPP/ pNPP субстрат / sustrato pNPP/ Υπόστρωμα pNPP/ substrato pNPP/ pNPP substrát/ pNPP-substrat/ pNPP-substrat/ Substrat pNPP/ substrát pNPP/ substrat pNPP/ pNPP-substrat

STOP	Stopplösung/ stopping solution/ solution d'arrêt/ soluzione di arresto/стоп-рaствop/ solución de parada/ διάλυμα διακοπής/ solução de paragem/ zastavovací roztok/ stopopløsning/ stopplösning/ roztwór zatrzymujący reakcję/ ukončovací roztok/ raztopina za ustavitev reakcije/ stoppeløsning
INFO	Gebrauchsanweisung, Zertifikat (Standardkurve und Auswertetabelle), CD/ instructions, certificate (standard curve and evaluation table), CD/ instructions, certificat (courbe de référence et tableau d'évaluation), CD/ istruzioni per l'uso, certificato (curva standard e tabella interpretativa), CD/ Инструкция по применению, сертификат (стандартная кривая и таблица для оценки), компактний диск /instrucciones, certificado (curva patrón y tabla de evaluación), CD/ Οδηγίες χρήσης, Πιστοποιητικό (πρότυπη καμπύλη και πίνακας υπολογισμού), CD/ instruções, certificado (curva padrão e tabela de avaliação), CD/ (standardní křivka a vyhodnocovací tabulka), CD/ brugsanvisning, certifikat (standardkurve og evalueringstabel), CD/ instruktioner, certifikat (standardkurva och utvärderingstabel), CD/ Instrukcje, certyfikat (krzywa standardowa i tabela do określania wyników/ CD/ pokyny, certifikát (štandardná krivka a hodnotiacia tabuľka), disk CD/ navodila, certifikat (standardna krivulja in ocenjevalna tabela), CD/ Instruksjoner, sertifikat (standardkurve og evalueringstabel), CD
RTU	gebrauchsfertig/ ready-to-use/ prêt à l'emploi/ pronto per l'uso/ готовый к использованию /listo para usar/ έτοιμο προς χρήση/ pronto a utilizar/ připravený k použití/ klar til brug/ bruksfærdig/ gotowy do użycia/ pripravené na použitie/ pripravljen za uporabo/ klar til bruk
CONC	Konzentrat/ concentrate/ concentré/ concentrato/ концентрат / concentrado/ Συμπύκνωμα/ concentrado/ koncentrát/ koncentrat/ koncentrat/ Konzentrat/ koncentrát/ koncentrat/ Konsentrat
DIL	verdünnen oder lösen in/ dilute or dissolve in/ diluez ou dissoudre dans/ diluire o sciogliere in/ разбавить или растворить в /diluir o disolver en/ αραιώση ή διάλυση σε/ diluir ou dissolver em/ naředit nebo rozpustit v/ fortynd eller opløs i/ späd eller lös i/ Rozcieńczyć lub rozpuścić w/ rozriediť alebo rozpustiť v/ razredčite ali raztopite v/ Fortynnes eller løses opp i
AQUA	destilliertes Wasser/ aqua detillata/ eau distillée/ acqua distillata/ дистиллированная вода /agua destilada/ αποσταγμένο νερό/ água destilada/ destilovaná voda/ destilleret vand/ destillerat vatten/ woda destylowana/ destilovaná voda/ destilirana voda/ Destillert vann
IVD	In-vitro Diagnostik Anwendung/ in-vitro diagnostic use/ utilisation en diagnostic in-vitro/ uso diagnostico in vitro/ использование в диагностике ин-витро /uso diagnóstico in-vitro/ Διάγνωση, χρήση in-vitro/ para diagnóstico <i>in vitro</i> / diagnostické použití in-vitro/ til in-vitro diagnostik/ <i>in vitro</i> -diagnostisk användning/ do diagnostyki in vitro/ diagnostické použitie in-vitro/ uporaba pri diagnostiki <i>in vitro</i> / In vitro-diagnostisk bruk
	Gebrauchsanweisung beachten/ consult instructions for use/ se référer à la notice d'instruction/ consultare le istruzioni per l'uso/ ознакомьтесь с инструкцией по использованию/ consúltense las instrucciones de uso/ συμβουλευτείτε τις οδηγίες χρήσης/ consultar as instruções de utilização/ čtěte návod k použití/ se brugsanvisningen/ se bruksanvisningen/ zapoznaj się z instrukcją stosowania/ dodržuj návod na použití/ glejte navodila za uporabo/ se bruksanvisningen/ figyelembe kell venni a használati utasítást

SERION ELISA *classic*

102	Masern Virus / Measles Virus / Rougeole	125	Leptospira
103	Mumps Virus / Parotitis virus / Oreillons	126	Parainfluenza Virus
104	Varicella-Zoster Virus (VZV)	127	Mycoplasma pneumoniae
105	Herpes simplex Virus 1/2	128	Adenovirus
1051	Herpes simplex Virus 1	129	Röteln Virus / Rubella virus / virus de rubéole
1052	Herpes simplex Virus 2	130	Diphtherie / Diphtheria
106	Legionella pneumophila 1-7	1311	Coxiella burnetii (Q-Fieber) Phase 1 / Coxiella burnetii (Q-fever) phase 1
107	Echinococcus	1312	Coxiella burnetii (Q-Fieber) Phase 2 / Coxiella
108	Tetanus	132	Aspergillus fumigatus
109	Cytomegalovirus	133	Enterovirus
110	Toxoplasma gondii	134	Coxsackievirus
112	FSME Virus / TBE Virus	135	Echovirus
113	Resp. Syncytial Virus (RSV)	1361	Epstein-Barr Virus VCA
114	Dengue Virus/ Dengue	1362	Epstein-Barr Virus EBNA 1
116	Brucella	1363	Epstein-Barr Virus Early Antigen
117	Candida albicans	137	Chlamydia
118	Helicobacter pylori	1371	Chlamydia pneumoniae
120	Bordetella pertussis	1372	Chlamydia trachomatis
1201	Bordetella pertussis Toxin	138	Yersinia
121	Borrelia burgdorferi	139	Campylobacter jejuni
122	Parvovirus B19	141	West Nile Virus
1231	Influenza A Virus	142	Francisella tularensis
1232	Influenza B Virus	147	Leishmania



Manufacturer

virion\serion

Institut Virion\Serion GmbH

Friedrich-Bergius-Ring 19
97076 Würzburg, Germany

Tel. +49 (0) 931 3045 0 Fax +49 (0) 931 3045 100

Mail info@virion-serion.de

Web www.virion-serion.de

09/2018