

Infectious diseases – serology

RIDASCREEN® Sero ELISAs – infection diagnostics from one source

- Single-point evaluation saves time and money
- Use of available WHO standards
- Parallel testing of different parameters and short incubation times
- Ready-to-use reagents suitable for use in multiple tests
- Easy evaluation by user-friendly software
- Validated for automated systems
- CE approved



All RIDASCREEN® Sero ELISA test kits contain 2 additional controls for broader quality assurance purposes

Demands on modern serologic diagnostics

R-Biopharm test systems for infectious diseases cover all important areas of modern serological diagnostics. All test kits are highly specific and sensitive for the respective pathogens.

Individual patient analysis leads to multiple determinations which must be tested in parallel. Test specific reagents and different incubation times require an amount of time and work that can hardly be handled.

In our RIDASCREEN® Sero ELISA product group the number of reagents is reduced to a minimum by offering common buffers and conjugates. Identical incubation times also make the simultaneous analysis of different tests easier. Thus, RIDASCREEN® Sero ELISAs fulfil the essential requirements for an

automatic processing on modern ELISA systems that help to facilitate procedures in the laboratory. A single-point calibration of the standard curve reduces the number of standards to a single one and therefore keeps costs to the minimum. Interpretation of results is quick and easy by using RIDASOFT® Win.NET software.

For enabling an international comparability of the test results R-Biopharm uses WHO-standards for several parameters (IU/ml).

Antigens – the key to success

The core of every single ELISA antibody detection assay is the antigen-coated microtiter plate. We exercise the greatest care when selecting our antigens. They come from laboratories that are specialized in antigen production. Only in this way quality of the antigens is guaranteed. Furthermore, via constant involvement of reference laboratories concerning various parameters we ensure that the latest developments in the antigen field are always

taken into account. Beside choosing the best antigen, the crucial factor affecting the quality of a test is the coating technique. Only the right conditions during the coating process will ensure that all the antigen epitopes perform their optimal presentation for binding to the antibodies. At the same time, any non-specific binding sites have to be blocked – a balancing act in every ELISA development.

Additional control samples for broader quality assurance

In Germany the new Guidelines of the German Medical Association for Quality Assurance of Laboratory Medical Examinations (RiliBÄK) stipulate additional control samples for medical laboratories allowing a significant enhancement of internal quality assurance for laboratory-specific tests. In accordance with these guidelines R-Biopharm

now supplies, besides the standard and the negative control, two additional control samples for all RIDASCREEN® Sero ELISA test kits, offering therefore an extremely high standard on quality assurance.

Rely on our more than 20 years experience in ELISA development and production

The significance of quantitative analysis in serology

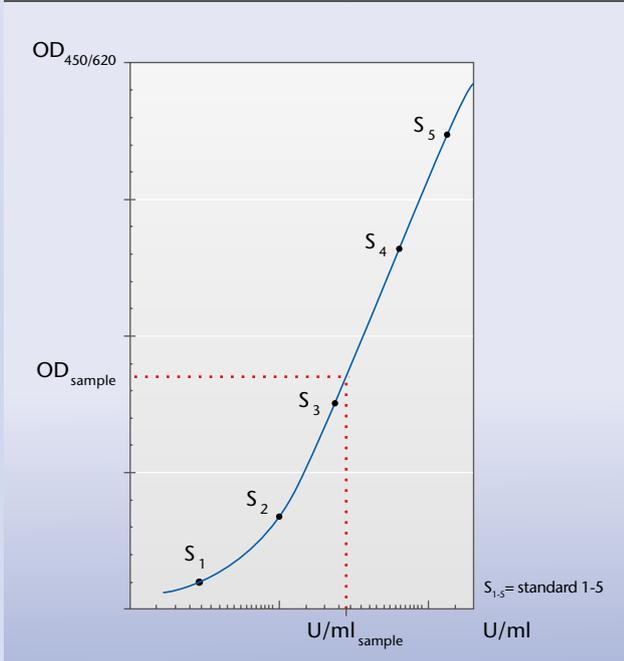
In case of serological ELISA tests a simple positive or negative evaluation is often not sufficient. In many human sera IgG antibodies against various types of pathogens are detectable without any evidence of acute infection. Similarly IgM and IgA antibodies can persist for any length of time after infection or decline slowly. Changes in the antibody titer (increase or decrease) detected while successive testing of serum samples finally give information about the situation of the patient. For state-of-the-art ELISA tests, quantitative analysis of the antibody concentration (antibody titer) is therefore highly desirable. Beside the role in monitoring patients, quantification is also important for vaccination

monitoring. By vaccination a person with high antibody titers painful or dangerous reactions could be induced. An important prerequisite for this application is the adaptation of the test to an international standard serum. This is the only possibility of establishing an independent quantification in international units (IU/ml) and thereby enabling a comparative assessment of the test results.

Serological tests that only permit positive/negative assessments or calculate an index value from sample and cut-off values show a definite disadvantage compared to quantifiable tests.

Quantification using a standard curve

Titer determination of a sample in U/ml



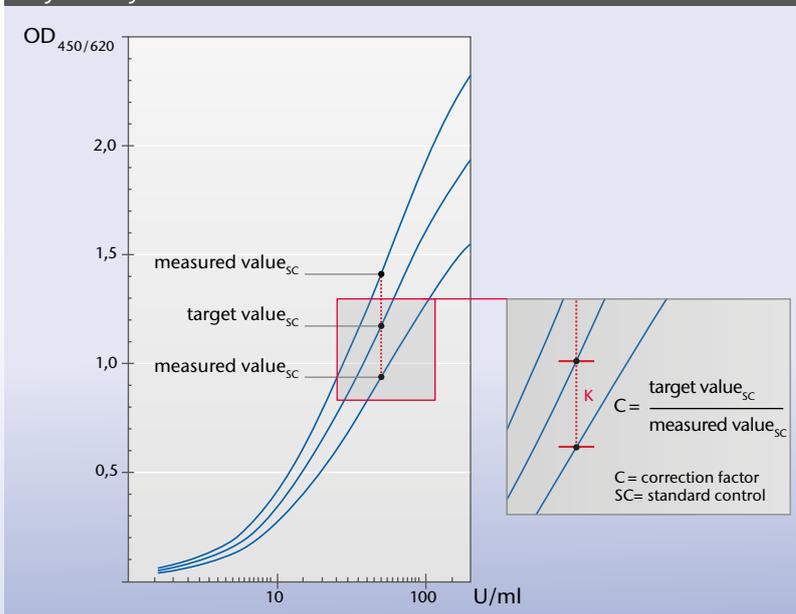
To determine the standard curve required for quantification, a standard serum should be diluted to give at least five titer solutions of different strength (titer level). Each diluted solution is examined during the test. The results show the run of the standard curve. The more titer levels are taken into account, the more exact the calculation of the typical sigmoidal-shaped standard curve in an immunological test will emerge. The antibody titer of an unknown sample can then be read directly from the standard curve.

Economical single-point quantification

Due to the fluctuations in activity during a series of test runs (inter-assay variance) the standard curve normally has to be recalculated for each new test run. However, if an ELISA meets certain quality requirements, it is not necessary to create a totally new standard curve by testing five or six standard concentrations. Variations in the standard curve from test run to test run are usually very slight. The relationship of the individual standard curves to each other is a simple mathematical one. A correction factor records the deviations.

Prerequisite is the extremely equable coating on our microtiter plates within an ELISA batch with low inter-assay variance. This enables us to include a pre-calculated, batch-specific standard curve in every test kit we supply. The day-to-day deviations from this standard curve are calculated by the extinction value of a standard control serum that is part of every kit. The current serum value is set in proportion to the batch-specific value (target value). This determines the correction factor which is then used to calculate the current run of the curve.

Day-to-day variation of the standard curve



Therefore, you get with only one standard economically a quantitative test result instead of using five or six. Matching the curve to international standard serum enables the result to be displayed in International Units (IU/ml). International standards do not exist for all parameters. In such cases the result is shown in test-specific units (U/ml).

Software-supported evaluation

The evaluation is very easy with RIDASOFT® Win.NET, our specially developed software. Once the batch-specific parameters are entered, the software calculates the result from the patient samples.

Simultaneously parallel during the test run the software checks whether the quality assurance criteria were maintained.

RIDASCREEN® Sero conjugates

Different infectious agents induce immune responses of varying strengths. Therefore, in modern ELISA antibody detection assays, the different components for each parameter must be perfectly matched. By using the same reagents there is a risk to lose this fine-tuning. By providing two different conjugate concentrations within each

immunoglobulin class, we succeeded in adjustment of each parameter individually. Thus, you find an HD or LD conjugate (high and low dilution, respectively) in our RIDASCREEN® Sero ELISAs. Despite the use of uniform reagents, optimal adjustment of each test is guaranteed.

RIDASCREEN® colour code

To prevent confusion concerning the different immunoglobulin classes, we offer colour-coded reagents. The colours on the lids indicate the immunoglobulin class (IgA, IgG, IgM). Additionally the reagents themselves are dyed in the same colour, facilitating to do a visual check while pipetting.



Automation

All the RIDASCREEN® Sero ELISAs were checked for their ability using them in commercial ELISA machines. In this context, using common reagents for different parameters, the RIDASCREEN® Sero ELISAs achieve the essential requirements for automatic processing.

Are you interested in complete solution for your laboratory (ELISA and automation)?
Feel free to contact us.

Quality assurance

Our ELISAs all carry the CE mark. Each of the reagents as well as the complete test kits are subject to regular inspection. As a certified corporation in

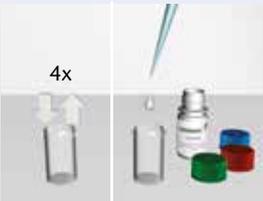
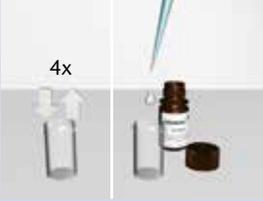
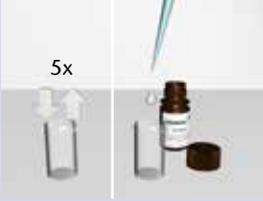
accordance with DIN EN ISO 9001 and DIN EN ISO 13485, we meet any quality demands you expect from a business partner.

Test procedure for the RIDASCREEN® ELISAs

Dilute the serum with the sample buffer according to the test instructions.
Insert the required microtiter strips into the holder.

RIDASCREEN® Sero ELISAs

RIDASCREEN® Parasite ELISAs

| | | | | |
|---|---|---|--|--|
| 1 |  | <p>Add 100 µl of control and diluted serum sample</p> |  | <p>Add 100 µl of control and diluted serum sample</p> |
| | 30 min | Incubate at 37 °C | 15 min | Incubate at rt (20 - 25 °C) |
| 2 |  | <p>Wash 4 times with 300 µl wash buffer</p> <p>Add 100 µl of the conjugate (SeroA, SeroG or SeroM)</p> |  | <p>Wash 5 times with 300 µl wash buffer</p> <p>Add 100 µl of the conjugate</p> |
| | 30 min | Incubate at 37 °C | 15 min | Incubate at rt (20 - 25 °C) |
| 3 |  | <p>Wash 4 times with 300 µl wash buffer</p> <p>Add 100 µl of the substrate</p> |  | <p>Wash 5 times with 300 µl wash buffer</p> <p>Add 100 µl of the substrate</p> |
| | 30 min | Incubate at 37 °C | 15 min | Incubate at rt (20 - 25 °C) |
| 4 |  | <p>Add 100 µl of the stop reagent</p> <p>Photometric evaluation at 450 nm Reference wavelength ≥ 620 nm</p> |  | <p>Add 50 µl of the stop reagent</p> <p>Photometric evaluation at 450 nm Reference wavelength ≥ 620 nm</p> |

Product overview

Infectious diseases/antibody detection

Sero ELISA

| Product | Description | Tests | Matrix | Art. No. |
|---|---|-------|--------|----------|
| Virus | | | | |
| Enzyme immunoassays | | | | |
| RIDASCREEN® Masern/Measles Virus IgG | Specific detection of IgG or IgM antibodies against Measles virus. IgG-analysis in international units (mIU/ml) | 96 | Serum | K5421 |
| Masern/Measles Virus IgM | | 96 | Serum | K5431 |
| RIDASCREEN® Mumps Virus IgG | Specific detection of IgG or IgM antibodies against Mumps virus | 96 | Serum | K5521 |
| Mumps Virus IgM | | 96 | Serum | K5531 |
| RIDASCREEN® Parvovirus B19 IgG | Specific detection of IgG or IgM antibodies against Parvovirus B19. Detection of antibodies against recombinant VP1 and VP2. Differentiation between acute and past infection with Parvovirus B19 IgG analysis in international units (IU/ml) | 96 | Serum | K6021 |
| Parvovirus B19 IgM | | 96 | Serum | K6031 |
| RIDASCREEN® Hantavirus Dobrava/Hantaan IgG | Specific detection of IgG or IgM antibodies against the Dobrava and Hantaan serotype of Hantavirus | 96 | Serum | K9121 |
| Hantavirus Dobrava/Hantaan IgM | | 96 | Serum | K9131 |
| RIDASCREEN® Hantavirus Puumala IgG | Specific detection of IgG or IgM antibodies against the Puumala serotype of Hantavirus | 96 | Serum | K9221 |
| Hantavirus Puumala IgM | | 96 | Serum | K9231 |
| Bacteria | | | | |
| Enzyme immunoassays | | | | |
| RIDASCREEN® Bordetella IgA | Specific detection of IgA, IgG or IgM antibodies against <i>Bordetella pertussis</i> and <i>Bordetella parapertussis</i> . Differentiation between infections and immune status after vaccination | 96 | Serum | K2511 |
| Bordetella IgG | | 96 | Serum | K2521 |
| Bordetella IgM | | 96 | Serum | K2531 |
| RIDASCREEN® Borrelia IgG | Specific detection of IgG or IgM antibodies against <i>Borrelia burgdorferi sensu lato</i> | 96 | Serum | K3221 |
| Borrelia IgM | | 96 | Serum | K3231 |
| RIDASCREEN® Helicobacter IgA | Specific detection of IgA or IgG antibodies against <i>Helicobacter pylori</i> | 96 | Serum | K2311 |
| Helicobacter IgG | | 96 | Serum | K2321 |
| RIDASCREEN® Mycoplasma pneumoniae IgA | Specific detection of IgA, IgG or IgM antibodies against <i>Mycoplasma pneumoniae</i> | 96 | Serum | K4311 |
| Mycoplasma pneumoniae IgG | | 96 | Serum | K4321 |
| Mycoplasma pneumoniae IgM | | 96 | Serum | K4331 |
| Bacteria toxins | | | | |
| Enzyme immunoassays | | | | |
| RIDASCREEN® Bordetella PT IgA | Specific detection of IgA or IgG antibodies against toxin of <i>Bordetella pertussis</i> IgA and IgG analysis in international units (IU/ml) | 96 | Serum | K2611 |
| Bordetella PT IgG | | 96 | Serum | K2621 |
| RIDASCREEN® Diphtherie IgG | Specific detection of IgG antibodies against Diphtherietoxoid. Analysis in international units (IU/ml) | 96 | Serum | K3821 |
| RIDASCREEN® Tetanus IgG | Specific detection of IgG antibodies against Tetanustoxoid. Analysis in international units (IU/ml) | 96 | Serum | K3721 |

Product overview

Infectious diseases/antibody detection

Infectious diseases

| Product | Description | Tests | Matrix | Art. No. |
|-----------------------------------|---|----------------------------|--------------|--|
| Microspot arrays | | | | |
| SeraSpot® Anti-Borrelia-10 IgG | Specific detection of IgG antibodies against <i>Borrelia burgdorferi sensu lato</i> | 1 x 48 1 x 96 2 x 96 | Serum/plasma | SP-006-10 G-S6 SP-006-10 G-S12 SP-006-10 G-S24 |
| SeraSpot® Anti-Borrelia-10 IgM | Specific detection of IgM antibodies against <i>Borrelia burgdorferi sensu lato</i> | 1 x 48 1 x 96 2 x 96 | Serum/plasma | SP-006-10 M-S6 SP-006-10 M-S12 SP-006-10 M-S24 |
| SeraSpot® Anti-Yersinia-6 IgA | Specific detection of IgA antibodies against <i>Yersinia enterocolitica</i> | 1 x 48 1 x 96 2 x 96 | Serum/plasma | SP-005-6 A-S6 SP-005-6 A-S12 SP-005-6 A-S24 |
| SeraSpot® Anti-Yersinia-6 IgG | Specific detection of IgG antibodies against <i>Yersinia enterocolitica</i> | 1 x 48 1 x 96 2 x 96 | Serum/plasma | SP-005-6 G-S6 SP-005-6 G-S12 SP-005-6 G-S24 |
| SeraSpot® Anti-Helicobacter-6 IgA | Specific detection of IgA antibodies against <i>Helicobacter pylori</i> | 1 x 48 1 x 96 | Serum/plasma | SP-007-6 A-S6 SP-007-6 A-S12 SP-007-6 A-S24 |
| SeraSpot® Anti-Helicobacter-6 IgG | Specific detection of IgG antibodies against <i>Helicobacter pylori</i> | 1 x 48 1 x 96 2 x 96 | Serum/plasma | SP-007-6 G-S6 SP-007-6 G-S12 SP-007-6 G-S24 |
| SeraSpot® Anti-Treponema-4 IgG | Specific detection of IgG antibodies against <i>Treponema pallidum</i> | 1 x 48 1 x 96 | Serum/plasma | SP-010-4 G-S6 SP-010-4 G-S12 |
| SeraSpot® Anti-Treponema-4 IgM | Specific detection of IgM antibodies against <i>Treponema pallidum</i> | 1 x 48 1 x 96 | Serum/plasma | SP-010-4 M-S6 SP-010-4 M-S12 |
| SeraSpot® Anti-EBV-4 IgG | Specific detection of IgG antibodies against Epstein-Barr-Virus | 1 x 96 | Serum/plasma | SP-013-4 G-S12 |
| SeraSpot® Anti-EBV-3 IgM | Specific detection of IgM antibodies against Epstein-Barr-Virus | 1 x 96 | Serum/plasma | SP-013-3 M-S12 |
| SeraSpot® Anti-Parvovirus-6 IgG | Specific detection of IgG antibodies against Parvovirus | 1 x 48 | Serum/plasma | SP-012-6 G-S6 |
| SeraSpot® Anti-Parvovirus-5 IgM | Specific detection of IgM antibodies against Parvovirus | 1 x 48 | Serum/plasma | SP-012-5 M-S6 |

Mosquito-borne diseases

| Enzyme immunoassays | | | | |
|---|---|----|--------------|-------|
| RIDASCREEN® Chikungunya Virus IgG capture | Specific detection of IgG or IgM antibodies against Chikungunya virus | 96 | Serum/plasma | K8121 |
| Virus IgM μ -capture | | 96 | Serum/plasma | K8122 |
| RIDASCREEN® Dengue Virus IgG | Specific detection of IgG or IgM antibodies against Dengue virus | 96 | Serum/plasma | K8221 |
| Dengue Virus IgM μ -capture | | 96 | Serum/plasma | K8222 |
| RIDASCREEN® Malaria Ab-Screening | Specific detection of IgG and IgM antibodies against Plasmodium | 96 | Serum/plasma | K8341 |
| RIDASCREEN® Zika Virus IgG capture | Specific detection of IgG or IgM antibodies against Zika virus | 96 | Serum/plasma | K8421 |
| Zika Virus IgM μ -capture | | 96 | Serum/plasma | K8431 |

Product overview

Infectious diseases/antibody detection

Tick-borne encephalitis

| Product | Description | Tests | Matrix | Art. No. |
|-----------------------------|--|-------|--------|----------|
| Enzyme immunoassays | | | | |
| RIDASCREEN® FSME/TBE IgG | Specific detection of IgG or IgM antibodies against tick-born encephalitis (TBE) | 96 | Serum | K3421 |
| FSME/TBE IgM | | 96 | Serum | K3431 |



Parasite diagnostics

| | | | | |
|--|--|----|------------------------|----------|
| Enzyme immunoassays | | | | |
| RIDASCREEN® Echinococcus IgG | Specific detection of IgG antibodies against <i>Echinococcus granulosus</i> and <i>Echinococcus multilocularis</i> | 96 | Serum | K7621 |
| RIDASCREEN® Entamoeba histolytica IgG | Specific detection of IgG antibodies against <i>Entamoeba histolytica</i> | 96 | Serum | K1721 |
| RIDASCREEN® Leishmania IgG | Specific detection of IgG antibodies against <i>Leishmania infantum</i> | 96 | Serum | K7321 |
| RIDASCREEN® Taenia solium IgG | Specific detection of IgG antibodies against the larval forms of <i>Taenia solium</i> (cysticercosis) | 96 | Serum | K7721 |
| RIDASCREEN® Toxocara IgG | Specific detection of IgG antibodies against <i>Toxocara canis</i> | 96 | Serum | K7421 |
| Enzyme immunoassays | | | | |
| NovaLisa™ Trichinella spiralis IgG | Specific detection of IgG antibodies against <i>Trichinella spiralis</i> | 96 | Serum/plasma (citrate) | TRIG0480 |



Chlamydia diagnostics

| | | | | |
|---|--|----|-------|---------|
| Enzyme immunoassays | | | | |
| RIDASCREEN® Chlamydia IgG/IgM | Specific detection of IgG or IgM antibodies against LPS antigen (LPS = lipopolysaccharide) of <i>Chlamydia</i> | 96 | Serum | KGM3101 |
| RIDASCREEN® Chlamydia trachomatis IgA Chlamydia trachomatis IgG/ IgM | Specific detection of IgA, IgG or IgM antibodies against outer membrane protein complex (COMP = Complexes of Outer Membrane Proteins) of <i>Chlamydia trachomatis</i> | 96 | Serum | K2911 |
| | | 96 | Serum | KGM2901 |
| RIDASCREEN® Chlamydophila pneumoniae IgA Chlamydophila pneumoniae IgG Chlamydophila pneumoniae IgM | Specific detection of IgA, IgG or IgM antibodies against outer membrane protein complex (COMP = Complexes of Outer Membrane Proteins) of <i>Chlamydophila pneumoniae</i> | 96 | Serum | K2811 |
| | | 96 | Serum | K2821 |
| | | 96 | Serum | K2831 |

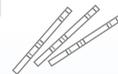


Product overview

Infectious diseases/antibody detection

Line blots for specific antibody detection

| Product | Description | Tests | Matrix | Art. No. |
|---|---|----------|----------------|------------------|
| Line blots | | | | |
| RIDA®LINE Parvovirus B19 IgG Parvovirus B19 IgM | Specific detection of IgG or IgM antibodies against Parvovirus B19 with recombinant antigens. Line blots allow differentiation between acute and past infection with Parvovirus B19. Indicative for a probably persistent Parvovirus B19 infection | 20 20 | Serum Serum | LB6023 LB6033 |
| RIDA® Aviditätsreagenz | Reagent for avidity testing in Line blots | 25 | Serum | LB0023Z03 |



Immunofluorescence assays for antibody detection

| Immunofluorescence assays | | | | |
|--|---|---------|-------|----------|
| RIDA®FLUOR Legionella IgG (3 Pools) | Row 1: SG 1 - 6 Row 2: SG 7 - 14 Row 3: L. boz-dum-gor-jord-longb-mic Immunofluorescence assay for detection of IgG antibodies against <i>Legionella pneumophila</i> serogroup 1 - 14 and six non-pneumophila species of <i>Legionella</i> | 10 x 30 | Serum | I8521 |
| Slides for immunofluorescence assays | | | | |
| RIDA®FLUOR Legionella IgG Slides (3 Pools) | Row 1: SG 1 - 6 Row 2: SG 7 - 14 Row 3: L. boz-dum-gor-jord-longb-mic | 10 x 30 | Serum | I8525 |
| Controls for immunofluorescence assays | | | | |
| RIDA®FLUOR Legionella IgG Negative control | Negative control IgG | 0.2 ml | Serum | I8521C00 |
| RIDA®FLUOR Legionella IgG Positive control | Positive control IgG | 0.2 ml | Serum | I8521C01 |



Accessories for RIDASCREEN® antibody detection tests

| | | | | |
|--------------------|--|----|-------|-------|
| RIDA® RF-Absorbens | Anti-human IgG for absorption of rheumatoid factors (RF) and IgG antibodies in human serum or plasma | 50 | Serum | Z0202 |
|--------------------|--|----|-------|-------|



Product overview

Infectious diseases/antibody detection

Autoimmune diseases

| Product | Description | Tests | Matrix | Art. No. |
|------------------------------------|--|----------------------------|--------------|--|
| Microspot arrays | | | | |
| <i>SeraSpot</i> ® ANA-12 IgG | Specific detection of IgG antibodies against 12 nuclear and cytoplasmatic antigens | 1 x 48 1 x 96 2 x 96 | Serum/plasma | SP-002-12 G-S6 SP-002-12 G-S12 SP-002-12 G-S24 |
| <i>SeraSpot</i> ® ANA-17 IgG | Specific detection of IgG antibodies against 17 nuclear and cytoplasmatic antigens | 1 x 48 1 x 96 2 x 96 | Serum/plasma | SP-002-17 G-S6 SP-002-17 G-S12 SP-002-17 G-S24 |
| <i>SeraSpot</i> ® HepAk-7 IgG | Specific detection of IgG antibodies in autoimmune liver diseases | 1 x 48 1 x 96 2 x 96 | Serum/plasma | SP-004-7 G-S6 SP-004-7 G-S12 SP-004-7 G-S24 |
| <i>SeraSpot</i> ® Vaskulitis-3 IgG | Specific detection of IgG antibodies in systemic vasculitis | 1 x 48 1 x 96 2 x 96 | Serum/plasma | SP-003-3 G-S6 SP-003-3 G-S12 SP-003-3 G-S24 |



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