SERION ELISA classic tests are qualitative and quantitative immunoassays for the detection of human antibodies directed against specific antigens of bacteria, viruses, fungi and parasites in serum, plasma or, when indicated, cerebrospinal fluid. The serological tests for the diagnosis of infectious diseases are designed to fulfill all requirements on modern in vitro diagnostics.

**SERION ELISA classic Immunoassays**

- Ready-to-use, colored and barcoded reagents optimized for quality assured handling
- Buffer and conjugate solutions are suitable for use in multiple tests in order to facilitate automation
- Consistent incubation times under defined conditions at 37 °C allow for the combination of multiple SERION ELISA classic IgA, IgG and IgM immunoassays in one test run
- High cost efficiency is guaranteed by using break-apart microtiter strips and the economical single-point calibration
- Exact quantification of the pathogen-specific IgA, IgG and IgM antibody activity is achieved by using a standard curve based on the precise 4 parameter logistic function (4 PL)
- Interpretation of test results is fast and easy with one of the various SERION software solutions
- External SERION ELISA controls offer a high standard on quality assurance in accordance with modern quality management guidelines
**Short Insight into the humoral Immune Response**

During the normal course of an infection the B-lymphocytes of the immune system manufacture a range of antibodies which are classified as e.g. IgM, IgG or IgA. Antibodies of the different classes are responsible for various effector functions during the immune reaction. In the course of a primary infection, IgM antibodies are produced first. Since their activity decreases after a few weeks, IgM antibodies in human serum samples are usually a marker for an acute or fresh infection. Subsequently, IgG antibodies are produced, which often persist life-long. A significant increase in the IgG antibody activity in human serum samples is a characteristic marker for a subsequent infection. IgA class antibodies are detectable in serum samples in cases of infections of the mucosa of e.g. the respiratory or the gastrointestinal tract.

**Test Principle of 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. Therefore, the test strips of the SERION ELISA classic microtiter plate are coated with specific antigens of the pathogen of interest. If antibodies are present in serum samples, they will bind to the fixed antigen. A secondary antibody, which has been conjugated with the enzyme alkaline phosphatase, detects the immune complex. The colorless substrate p-nitrophenylphosphate is then converted into the colored product p-nitrophenol. The signal intensity of the reaction product is measured photometrically and proportional to the antibody activity in the sample.
SERION Antigens – Keys to Success

A deciding factor in the success and performance of any immunoassay is the pathogen-specific antigen. Therefore each individual antigen of every single SERION ELISA classic immunoassay is selected with greatest care. National and international cooperations with universities and research institutions provide for ongoing interchange of ideas with acknowledged experts. By working closely with partners throughout the world, Institut Virion\Serion GmbH is able to target its research and development activities to the needs of all parties and bring to market the new and innovative products and services that are relevant to the ever changing diagnostic environment. Based on more than 35 years of experience in the cultivation of pathogens and the purification of antigens more than 70 different, native and recombinant antigens are manufactured exclusively in the premises of Institut Virion\Serion GmbH in Würzburg, Germany, in order to establish SERION ELISA classic immunoassays of the highest quality.

Coating Technique for Microtiter Plates

Besides the selection of the optimal antigen, the coating technique is another crucial factor affecting the performance of immunoassays. Only optimal conditions during the coating process ensure that antigen epitopes perform their correct presentation for binding antibodies. In more than 35 years of experience in the development of immunoassays in different test formats, Institut Virion\Serion GmbH has optimized the coating process for each individual SERION ELISA classic immunoassay.

Interchangeable Test Reagents

Different pathogens induce immune responses of varying strength. As a consequence, ELISA immunoassays even from the same manufacturer are often based on many individual and test-specific components. Since positions in automates are limited, the use of many test-specific reagents can cause difficulties in parallel test processing, which is circumvented by the use of test-independent and interchangeable reagents of SERION ELISA classic immunoassays. On the other hand, the use of uniform test reagents can lead to low diagnostic efficiency values in individual immunoassays if a test level is not adjusted properly. By providing three different conjugate strengths for each immunoglobulin class, any SERION ELISA classic test can be optimally adjusted in order to guarantee highest diagnostic efficiencies despite the use of predominantly test-independent reagents.

SERION ELISA classic Product Categories

The SERION ELISA classic product portfolio of Institut Virion\Serion GmbH comprises immunoassays for...

- diagnosis of children’s diseases
- immune status control
- extended ToRCH diagnostics
- avidity determination
- neonatal diagnostics
- diagnosis of respiratory diseases
- diagnosis of Herpes Virus infections
- diagnosis of gastrointestinal diseases
- diagnosis of mycoses
- diagnosis of chlamydioses
- diagnosis of Enterovirus infections
- diagnosis of tropical diseases
- CSF diagnostics

SERION ELISA control

The requirements of modern quality management guidelines e. g. of the German Medical Association foresee the use of positive controls for laboratory tests in order to demonstrate compliance with the mandatory high standards. Therefore, Institut Virion\Serion GmbH offers external positive control sera for the qualitative and quantitative determination of antibodies when using SERION ELISA classic immunoassays. The ready-to-use SERION ELISA controls are, in addition to the controls supplied with the SERION ELISA classic test kits, supplementary reagents to determine validity of SERION ELISA classic test runs as well as the precision and reliability of the method. SERION ELISA controls are particularly recommended as an aid to internal quality management in accredited laboratories.
Highlights of SERION ELISA *classic* Immunoassays

- Comprehensive SERION ELISA *classic* product portfolio
- SERION ELISA *classic* Immunoassays for the analysis of serum, plasma and, when applicable, CSF samples
- Consistent incubation periods (60 min, 30 min, 30 min) under defined conditions at 37 °C for combination of SERION ELISA *classic* IgA, IgG and IgM immunoassays in one microtiter frame
- Ready-to-use, colored and barcoded test components, suitable for use in multiple SERION ELISA *classic* tests and optimized for quality assured handling and automation
- High cost efficiency by using break-apart microtiter strips and economical single-point calibration by use of a single standard serum
- Exact quantification of pathogen-specific IgA, IgG and IgM antibody activities by use of the precise 4 parameter logistic function (4 PL)
- Standardized evaluation of antibody activities calibrated with international standard preparations of the World Health Organization (WHO) with results expressed in (m)IU/ml, if available
- Fast and quantitative data evaluation by use of the software SERION *evaluate*, SERION easyANALYZE or the Microsoft® Excel®-based software-tool SERION *activity*
- Excellent diagnostic efficiency with high sensitivity and specificity values by use of carefully selected antigens and optimized coating conditions for microtiter plates
- High precision and linearity within the measurement range
- Detection of intrathecally synthesized antibodies for CSF diagnostics, if applicable
- Compatibility with conventional ELISA Washer and Reader systems
- Application on Immunomat™, Gemini, Dynex DSX®, Dynex DS2® and comparable automates
- CE-approved
- External positive SERION ELISA controls according to modern quality management guidelines