

## Intended Use

- Qualitative (IgM) and quantitative (IgA / IgG) detection of human antibodies in serum or plasma directed against Respiratory Syncytial Virus
- · Support in the diagnosis of acute respiratory diseases and differential diagnosis.

# Diagnostic Efficiency

The SERION ELISA *classic* Respiratory Syncytial Virus IgG and IgA tests were evaluated with a panel of 67 blood donor sera and 25 sera of patients with a suspected RSV infection. Due to the fact that the CFT does not differentiate between immunoglobulin classes, the results of IgA and IgG ELISA were summarized.

For the calculation of the performance parameters of the SERION ELISA *classic* Respiratory Syncytial Virus IgM test 115 sera of healthy blood donors and patients with suspected acute RSV infections were analyzed in comparison to the results obtained with a commercially available ELISA.

Product	Sensitivity	Specificity
SERION ELISA <i>classic</i> Respiratory Syncytial Virus IgA / IgG	>99%	95.0 %
SERION ELISA <i>classic</i> Respiratory Syncytial Virus IgM	>99%	97.2 %

## Precision

### SERION ELISA classic Respiratory Syncytial Virus IgA

Sample	Mean Value (OD)	Intraassay CV (%) (n=20)	Mean Value (OD)	Interassay CV (%) (n=10)
Serum 1	0.502	1.8	0.529	6.1
Serum 2	0.795	2.1	0.835	6.2
Serum 3	1.116	4.1	1.144	4.8

## SERION ELISA *classic* Respiratory Syncytial Virus IgG

Sample	Mean Value (OD)	Intraassay CV (%) (n=20)	Mean Value (OD)	Interassay CV (%) (n=10)
Serum 1	0.475	1.8	0.510	5.9
Serum 2	0.624	1.4	0.683	5.6
Serum 3	1.383	1.7	1.455	5.0

## SERION ELISA *classic* Respiratory Syncytial Virus IqM

Sample	Mean Value (OD)	Intraassay CV (%) (n=20)	Mean Value (OD)	Interassay CV (%) (n=10)
Serum 1	0.601	0.9	0.573	3.2
Serum 2	1.392	1.1	1.364	1.6
Serum 3	2.392	1.1	2.465	1.5

#### Pathogen

Human Respiratory Syncytial Viruses (RSV) are enveloped (-)ssRNA viruses belonging to the Paramyxoviridae family. The two subtypes, classified as A and B, are globally distributed and are primarily differentiated by the antigenic structures. Respiratory Syncytial Viruses cause diseases of the upper and lower respiratory tract, particularly in infants and the elderly.

#### Disease

Respiratory Syncytial Viruses are among the most important agents causing nosocomial respiratory diseases in infants, particular premature babies, immune compromised patients and the elderly.

They elicit damage to the ciliated epithelium of the respiratory tract, which can be accompanied by the formation of syncytia. The following immune reaction may result in cell detritus which can block the bronchi and lead to respiratory distress. Epidemiological studies document that almost all children at the age of two years have been exposed to the virus.

### Diagnosis

Antigen and antibody detection methods are important in the diagnosis of RSV infections. In serology, ELISA tests, which allow for the differentiation of IgA, IgG and IgM immunoglobulin classes, are of increasing importance.

## Highlights

- Use of an inactivated preparation of Respiratory Syncytial Viruses for the demonstration of IgA, IgG and IgM antibodies, independent of the RSV A or B subtype
- Sensitive determination of IgA and IgM antibodies for the detection of acute infections
- Exclusion of background seroprevalence of IgG antibodies resulting in the specific detection of clinically relevant antibody activities
- · Differentiation of acute from past infections
- Quantification of IgA and IgG antibody activities, starting in the clinically negative measurement range, for analysis of paired sera for monitoring at risk patients, disease stage progression and therapy control

Produkt	Bestell-Nr.
SERION ELISA <i>classic</i> Respiratory Syncytial Virus IgA	ESR113A
SERION ELISA <i>classic</i> Respiratory Syncytial Virus IgG	ESR113G
SERION ELISA <i>classic</i> Respiratory Syncytial Virus IgM	ESR113M

### **SERION ELISA control**

Please visit our website for more information.