

## Intended use

- Qualitative and quantitative detection of human antibodies in serum or plasma directed against pathogenic human Adenovirus serotypes
- · Support in the diagnosis of acute respiratory diseases and differential diagnosis
- · Detection of intrathecally synthesized IgG antibodies in cerebrospinal fluid

# Diagnostic Efficiency

Sensitivity and specificity of the SERION ELISA *classic* Adenovirus IgG test were determined by analysing 48 sera from patients with suspected infection as well as 48 blood donor sera in comparison to results obtained from the complement fixation test (CFT). The CFT does not detect IgA antibodies. However, sensitivity and specificity in comparison with the CFT were calculated presuming that the IgA antibody production after an infection and the production of complement binding antibodies takes place simultaneously.

The performance characteristics of SERION ELISA *classic* Adenovirus IgM test were assessed by the analysis of 113 serum samples from blood donors and patients with suspected acute Adenovirus infection using the commercially available ELISA test of a competitor as a reference.

Product	Sensitivity	Specificity
SERION ELISA <i>classic</i> Adenovirus IgA / IgG	92.6 %	91.3 %
SERION ELISA <i>classic</i> Adenovirus IgM	>99 %	98.2%

### Precision

#### SERION ELISA classic Adenovirus IgA

Sample	Mean value (OD)	Intraassay CV (%) (n=20)	Mean value (OD)	Interassay CV (%) (n=10)
Serum 1	0.292	8.6	0.354	9.2
Serum 2	0.733	4.7	0.818	4.1
Serum 3	1.119	2.3	1.198	5.2

Sample	Mean value (OD)	Intraassay CV (%) (n=20)	Mean value (OD)	Interassay CV (%) (n=10)
Serum 1	0.392	5.4	0.406	7.2
Serum 2	0.547	4.7	0.541	9.3
Serum 3	1.188	4.8	1.209	8.3

### SERION ELISA classic Adenovirus IgM

Sample	Mean value (OD)	Intraassay CV (%) (n=20)	Mean value (OD)	Interassay CV (%) (n=10)
Serum 1	0.399	3.8	0.325	5.7
Serum 2	0.834	1.3	0.779	2.7
Serum 3	2.489	1.3	2.516	1.3

#### Pathogen

Adenoviruses are dsDNA viruses with icosahedral symmetry and a diameter of 90 to 100 nm. They belong to the family of *Adenoviridae* and were discovered in isolates from adenoids. Approximately 50 subtypes have been identified as human pathogens, with subtypes 1 to 8, 40 and 41 occuring most frequently.

#### Disease

Adenoviruses are responsible for a wide range of different diseases. In most cases, infections present with ocular, respiratory or gastrointestinal manifestations. Additionally, urethral infections, as well as hepatitis and meningoencephalitis are possible. Keratoconjunctivitis epidemica is a particularly significant ocular noso-

comial infection. Patients with weakened immune systems are particularly susceptible to serious complications following infection with Adenoviruses, e.g. Acute Respiratory Distress Syndrome (ARDS). Sequelae may include persistent bronchitis, joint pain, dilative cardiomyopathy, type 1 diabetes and hearing deficits.

#### Diagnosis

Direct and indirect detection methods are used for the diagnosis of Adenovirus infectons. Due to the variety of clinical symptoms, which may be caused by Adenoviruses, serological investigations have become important for the differential diagnosis of respiratory tract infections.

# Highlights

- Use of an inactivated preparation of hexon proteins of Adenovirus Type 2 for the demonstration of antibodies, independent of the causative Adenovirus subtype
- Sensitive determination of IgM antibodies for the diagnosis of acute infections
- IgA detection for determination of acute reinfections
- Exclusion of background seroprevalence of IgA and IgG antibodies resulting in the specific detection of clinically relevant antibody activities

- Alternative IgA and IgG borderline ranges for children and adults
- Quantification of IgA and IgG antibody activities, starting in the clinically negative measurement range, for analysis of paired sera for disease stage monitoring and therapy control
- · Differentiation between acute and past infections
- Detection of intrathecally synthesized IgG antibodies for CSF diagnostics

Product	Order No.
SERION ELISA <i>classic</i> Adenovirus IgA	ESR128A
SERION ELISA <i>classic</i> Adenovirus IgG	ESR128G
SERION ELISA <i>classic</i> Adenovirus IgM	ESR128M

#### **SERION ELISA control**

Please visit our website for more information.