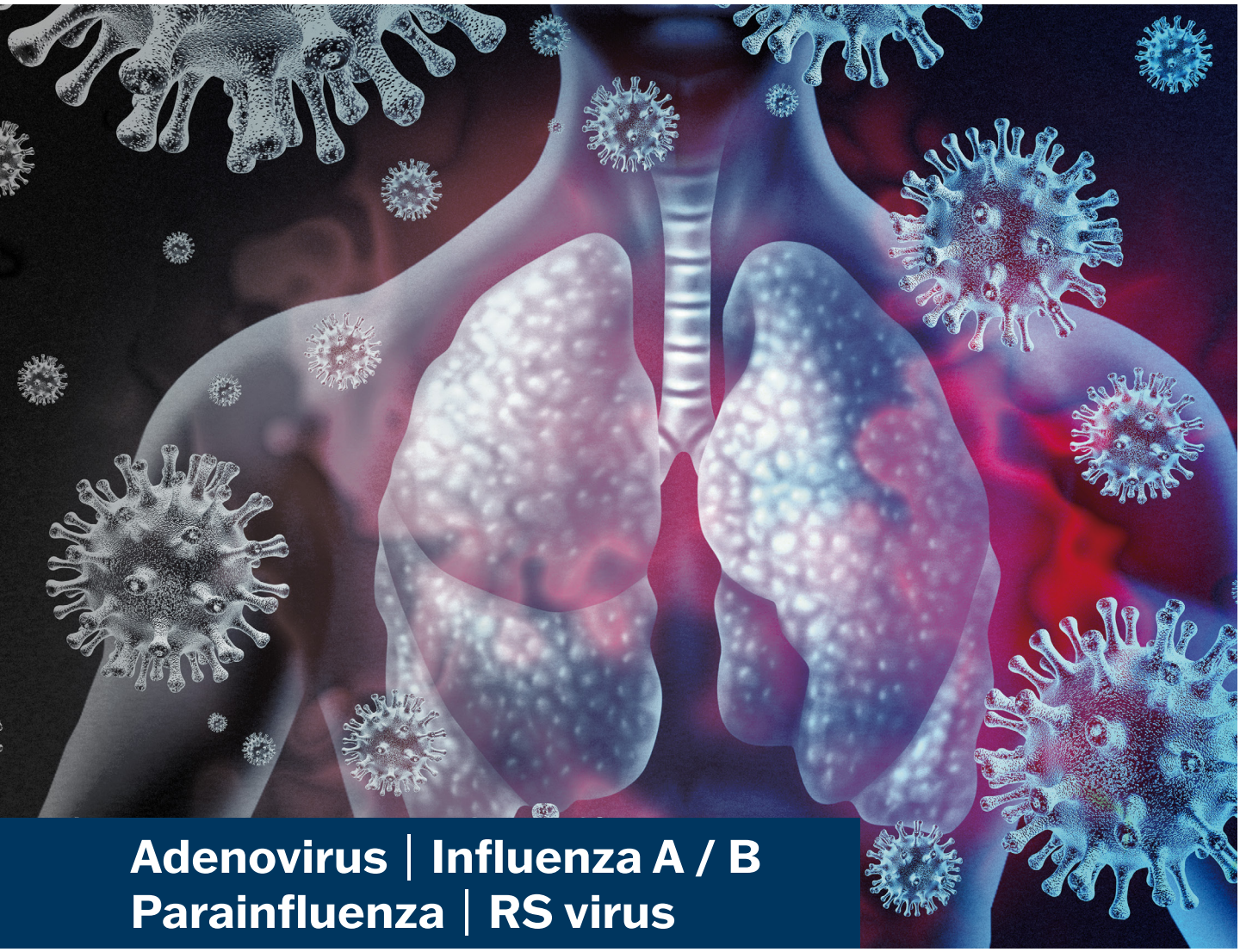


Adenovirus | Influenza A / B
Parainfluenza | RS virus

Enzyme immunoassays for the diagnostics of viral respiratory infections

ELISA kits are optimized and validated for detection of IgA, IgG and IgM antibodies in human serum and plasma

CE IVD

Diagnostic kits are intended for professional use in the laboratory.

BG TestLine®

Introduction

Adenoviruses are human and animal pathogens characterised by significant indifference to the environment. Acute adenoviral infections have an incubation period of 5–7 days. They spread via droplets or the faecal-oral route. Reinfections are common. The presence of IgG antibodies prevents a more serious course of infection. The viruses attack mainly the mucosa of the respiratory and digestive tract, but may affect also the conjunctiva and the cornea. They accumulate in epithelial cells and regional lymph nodes. The infection most often leads to respiratory tract affection (pharyngitis, tonsillitis, laryngitis, bronchitis, bronchiolitis or pneumonia). Adenoviruses cause pharyngoconjunctival fevers in the summer (the virus originates from swimming pool water) and keratoconjunctivitis epidemic. The intestinal form of adenovirus infections occurs mainly in children under one year of age.

Influenza is an acute respiratory viral airway disease with frequent epidemic occurrence in the population, especially in winter. The infection is transmitted via droplets. The virus spreads from the mucous membrane of the upper respiratory tract to the entire respiratory system. The virulence factors allow the virus to multiply and cause inflammation of the respiratory mucosa. The symptoms of the disease appear after an incubation period of about 1 to 3 days. The first symptoms of the disease include fever, often accompanied by chills, followed by dry cough, sore throat, muscle and joint pain, severe fatigue and rhinitis. The disease may require hospitalization in case of severe symptoms, especially in risk groups.

Three types of human influenza virus have been identified: A, B and C. Many of their antigenic variants have been reported. Haemagglutinin and neuraminidase surface antigens are essential for the immune response. Their antigenicity is constantly changing via mechanisms termed antigenic drift and shift. The development of a new influenza epidemic or pandemic is facilitated by antigen variability, as the new variants infect population only partially immune or, in extreme cases, completely susceptible to disease.

Determination of influenza type provides clinically and epidemiologically important data. Influenza B leads to more severe clinical course and epidemic spread of the virus. However, unlike influenza A, it does not cause pandemics.

Human parainfluenza viruses (HPIV) belong to a subgroup of paramyxoviruses (the Respirovirus and Rubulavirus genera) and cause infections primarily in young children, adolescents and immunodeficient individuals, but may affect everyone. The parainfluenza virus spreads in the population via air and droplets. Contrary to the influenza virus, it is prevalent especially outside of the winter period. These viruses are characterized by frequent reinfections. The vast majority of children over the age of five have antibodies against type 3 HPIV and 75% of them also against type 1 and 2. The incubation period lasts 2 to 7 days. There are four types of HPIV, labelled 1, 2, 3 and 4. Along with respiratory syncytial viruses (RS viruses), this represents one of the major viral pathogens of airway diseases. The disease is accompanied by serious clinical symptoms. In adults, the parainfluenza virus causes fever and laryngitis. Early signs include sudden headache, muscle and joint pain and fever. Tracheobronchitis with tachypnoea and dry cough develops if the lower respiratory tract is affected.

Type 1 HPIV causes severe pneumonia in newborns. This disease is characterized by high fever, dyspnoea and purulent sputum containing blood. Symptoms of meningitis sometimes develop at the same time.

Type 2 HPIV often causes acute laryngotracheobronchitis with laryngitis (so-called pseudocrup) in small and older children. The infection is initially manifested by catarrh-like symptoms, followed by tachypnoea, dry cough and stridor.

Type 3 HPIV is associated with bronchitis, bronchiolitis and pneumonia.

Human respiratory syncytial virus belongs to the paramyxoviridae family.

It spreads during the winter mainly in children and in infants. The incubation period is 2 to 6 days. The disease does not induce long-term immunity. Studies in adult volunteers have shown that reinfection is possible. It is believed that IgG antibodies are responsible for the mild course of the disease in adults, where cold-like symptoms usually develop. The immune system of children is not mature enough, and therefore infections (bronchitis, bronchiolitis, pneumonia) may be more severe, especially in infants. RS viruses are divided into two main groups (A and B) based on antigenic variability. Surface glycoproteins of the virus (contact glycoprotein

G and fusion glycoprotein F) lead to the production of virus-neutralizing antibodies.

G glycoproteins are highly variable, in contrast to F glycoproteins.

Diagnosis of Infection

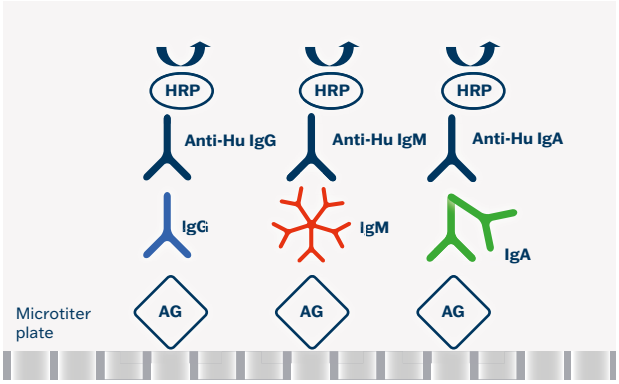
Diagnosis of the disease is based on the overall clinical picture, epidemiological anamnesis and laboratory tests.

Acute respiratory infections can be detected by isolation of the virus or serologically. Immunoenzymatic tests are important for the serological diagnostics because they are very sensitive and allow the detection of various antibodies classes. Responses of IgM-class antibody may sometimes be missing, whereas IgA-class antibodies may in some patients persist for months or even years. The detection of IgG antibodies in one sample does not indicate acute infection. An examination of paired samples needs to be done followed by demonstration of a significant increase in antibody titre.

ELISA

Test Principle

The assays are based on a sandwich type of ELISA method.



Summary Protocol

Step		Test steps
	1.	Dilute samples – serum/plasma 1:101 (10 µl + 1 ml)
	2.	Pipette controls and diluted samples 100 µl – blank = empty well
	3.	Incubate 30 min. at 37 °C
	4.	Aspirate and wash the wells 5 times
	5.	Add 100 µl Conjugate – blank = empty well
	6.	Incubate 30 min. at 37 °C
	7.	Aspirate and wash the wells 5 times
	8.	Add 100 µl Substrate (TMB-Complete) – Including blank
	9.	Incubate 30 min. at 37 °C
	10.	Add 100 µl Stopping solution – Including blank
	11.	Read colour intensity at 450 nm

Antigens

Adenovirus – native antigen

Influenza A – native nuclear antigen in combination with recombinant haemagglutinins, updated annually (A/Brisbane/02/2018/(H1N1)-like virus, A/Kansas/14/2017/(H3N2)-like virus)

Influenza B – native nuclear antigen in combination with recombinant haemagglutinins, updated annually (B/Colorado/06/2017-like virus)

Parainfluenza mix – antigen combination of three individual parainfluenza virus types (1,2,3)

RS virus – native antigen

Clinical Application

- Screening test for the detection of viral respiratory infections in humans

User Comfort

- Ready-to-use components
- Colour-coded components
- Interchangeable of components
- Breakable colour-coded microplate strips
- CUT-OFF and calibrators included
- Semiquantitative evaluation of results (Index of Positivity-IP)
- Sample diluent with RF-sorbent (IgM-class kits)

Advantages

- High diagnostic specificity and sensitivity, High reproducibility and dynamics of antibody response
- Identical assay procedure, short total assay time
- Customer support

Test Characteristics

ELISA	Diagnostic Sensitivity	Diagnostic Specificity
EIA Adenovirus IgA	96.0%	94.9%
EIA Adenovirus IgG	97.4%	92.3%
EIA Adenovirus IgM	75.0%	89.5%
EIA Influenza A IgA	93.8%	95.3%
EIA Influenza A IgG	96.5%	91.7%
EIA Influenza A IgM	90.9%	98.9%
EIA Influenza B IgA	94.1%	95.8%
EIA Influenza B IgG	92.3%	98.3%
EIA Influenza B IgM	93.8%	96.6%
EIA Parainfluenza mix IgA	93.6%	94.1%
EIA Parainfluenza mix IgG	98.6%	93.8%
EIA Parainfluenza mix IgM	94.2%	96.6%
EIA RSV IgA	95.0%	97.2%
EIA RSV IgG	97.5%	87.6%
EIA RSV IgM	75.0%	95.8%

EIA

SmartEIA

Ordering Information

ELISA

Cat. No.	Product	No. of Wells
AdA096	EIA Adenovirus IgA	96
AdG096	EIA Adenovirus IgG	96
AdM096	EIA Adenovirus IgM	96
InAA96	EIA Influenza A IgA	96
InAG96	EIA Influenza A IgG	96
InAM96	EIA Influenza A IgM	96
InBA96	EIA Influenza B IgA	96
InBG96	EIA Influenza B IgG	96
InBM96	EIA Influenza B IgM	96
PaiA96	EIA Parainfluenza mix IgA	96
PaiG96	EIA Parainfluenza mix IgG	96
PaiM96	EIA Parainfluenza mix IgM	96
RSA096	EIA RSV IgA	96
RSG096	EIA RSV IgG	96
RSM096	EIA RSV IgM	96
SK-AdA096	SmartEIA Adenovirus IgA	96
SK-AdG096	SmartEIA Adenovirus IgG	96
SK-AdM096	SmartEIA Adenovirus IgM	96
SK-InAA96	SmartEIA Influenza A IgA	96
SK-InAG96	SmartEIA Influenza A IgG	96
SK-InAM96	SmartEIA Influenza A IgM	96
SK-InBA96	SmartEIA Influenza B IgA	96
SK-InBG96	SmartEIA Influenza B IgG	96
SK-InBM96	SmartEIA Influenza B IgM	96
SK-PaiA96	SmartEIA Parainfluenza mix IgA	96

Ordering Information

Cat. No.	Product	No. of Wells
SK-PaiG96	SmartEIA Parainfluenza mix IgG	96
SK-PaiM96	SmartEIA Parainfluenza mix IgM	96
SK-RSA096	SmartEIA RSV IgA	96
SK-RSG096	SmartEIA RSV IgG	96
SK-RSM096	SmartEIA RSV IgM	96

SmartEIA kits are designed for automated processing using the Agility® analyser

TestLine®

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CERTIFIED
ISO 9001 · ISO 13485

Company is certified to the quality management system standards ISO 9001 and ISO 13485 for in vitro diagnostics.

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