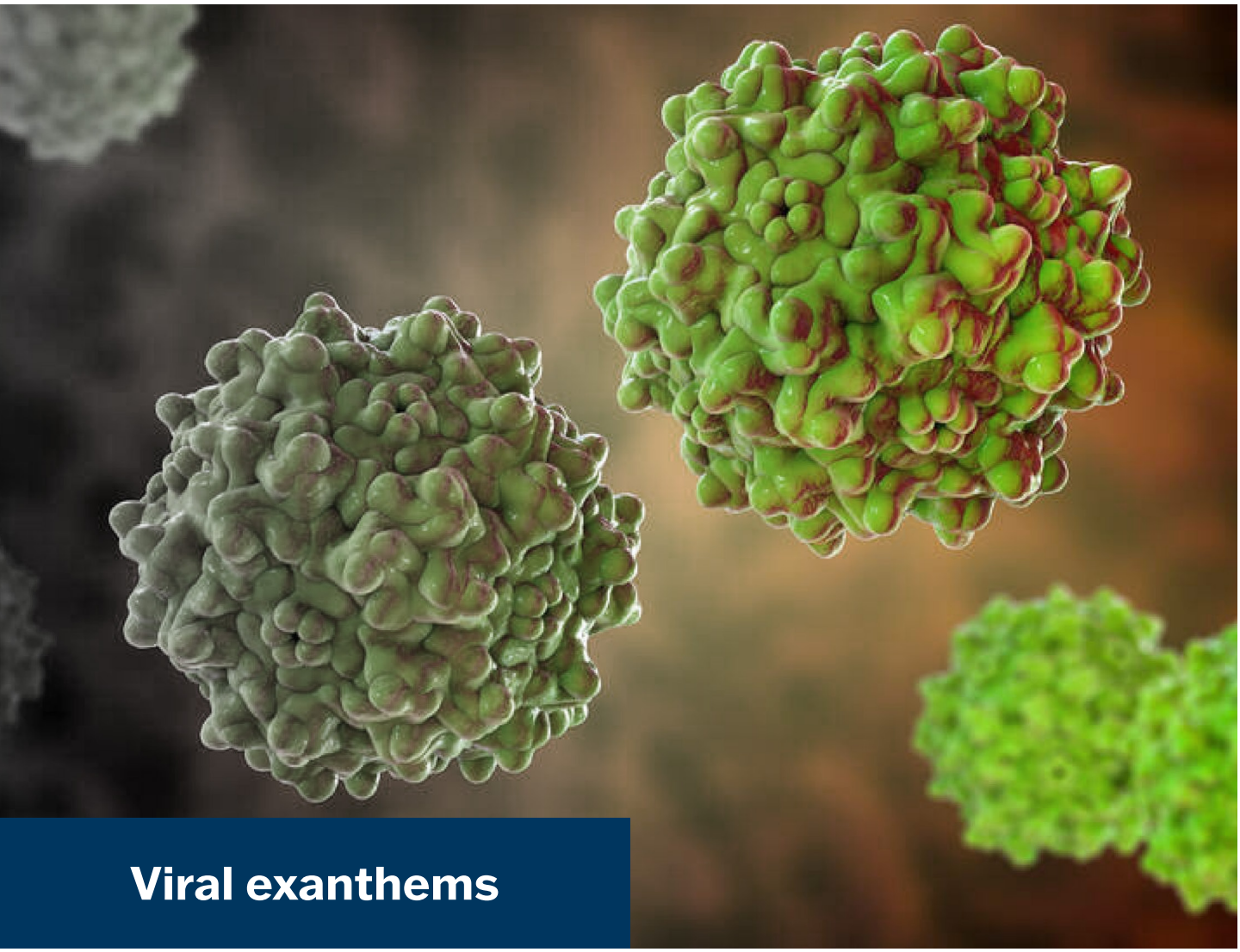


Viral exanthems

Enzyme immunoassays for the diagnosis of viral exanthems

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

CE IVD

Diagnostic kits are intended for professional use in the laboratory.

BG TestLine®

Introduction

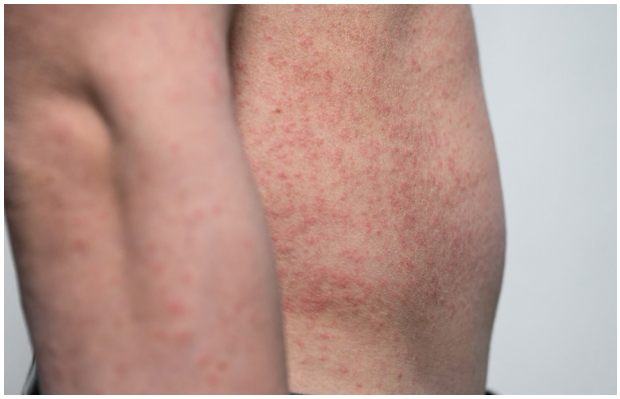
Measles are a highly contagious viral infectious disease caused by the measles virus, genus *Morbillivirus*, family *Paramyxoviridae*. This disease was one of the most common causes of child mortality worldwide under the age of five, and the incidence of measles has decreased since the introduction of vaccination.

The only natural host of measles virus is human. The disease is transmitted via droplet infection or direct contact with the patient. The incubation period is approximately 10 days, with high fever, cough, conjunctivitis and rhinitis being the first characteristic features of measles. A typical deep red rash appears around the ear and gradually spreads across the face to the entire body after 3–5 days. Characteristic white spots (so-called Koplik spots) may appear on the inside of the cheeks. The rash fades after a few days, and gradually subsides. The most difficult complications of measles include brain inflammation (encephalitis), pneumonia and otitis. After recovery, the patient is usually immune to measles for life.

The main prevention of measles is the general vaccination of children with MMR vaccine, which contains weakened measles, mumps and rubella viruses.

Mumps (parotitis epidemica) is an acute viral disease caused by an RNA virus from the *Paramyxoviridae* group.

Droplet-transmission is characteristic for the infections; saliva contaminated objects are less likely contributors to the spread of the disease. The disease occurs seasonally with the highest incidence in winter and spring, affecting mainly children aged 5–9 years and adolescents aged 15–19.



Measles

The incubation period of the disease is 2–3 weeks. The disease may occur asymptomatically, with relatively mild non-

specific symptoms (loss of appetite, elevated body temperature, headache), especially in children. A typical symptom of mumps is one-sided or bilateral painful swelling of parotid salivary glands, possibly also sublingual or submandibular salivary glands. Complications of the disease are more common in adults, the most severe being aseptic meningitis, orchitis, oophoritis and otitis.

The main means of mumps prevention is general vaccination of children using MMR vaccine, whereas the parotitic component of the vaccine induces the production of antibodies in about 90% of the vaccinated individuals.

Parvovirus B19 (Erythrovirus B19) belongs the Parvoviridae family. It is a common human pathogen. Man is its sole host. It is a non-enveloped single-stranded DNA virus. It consists of two structural proteins, VP1 and VP2, whereas VP2 is the major one and it forms approximately 96% of the total viral particle. Neutralizing antibodies are aimed against VP1.

Infection occurs throughout year with a mild growth at the end of spring. Infection may be transmitted via direct contact with the patient (droplets and even orofaecal transmission), blood derivatives or vertically from the mother to the foetus. Infection occurs in most immunocompetent individuals with no symptoms or with unspecified symptoms of mild upper respiratory tract infection. The virus multiplies in rapidly dividing haematopoietic cells of the bone marrow, and one of the signs may be a slight drop in the blood haemoglobin level.

Primary parvovirus B19 infection occurs most frequently in childhood as the so-called fifth disease (erythema infectiosum). The first phase of infection with unspecified symptoms (fever, chills, headache and muscle pain) occurs after an incubation period of 1–2 weeks. Specific manifestations of the disease develop in approximately two weeks (skin exanthema, typical rash in the area of the face, possibly joint pain).

Rubella is an exanthematic viral disease that occurs in childhood and adolescence and is transmitted by means of droplet infection or transplacentally. The disease is benign in most of the cases, characterized by fever, mild symptoms of upper respiratory tract infections, maculopapular rash, and swollen suboccipital and postauricular lymph nodes. Rubella, also known as German measles, can be very serious during early pregnancy stages when the virus affects the placenta, which in most of the cases leads to spontaneous abortion or congenital disorders. The fetus is most at risk if infection occurs during the first trimester with risk declining with length of pregnancy.

Reinfection is more likely to occur in vaccinated rather than in naturally immunized individuals and most of these reinfections occur without symptoms. Rubella reinfection during pregnancy rarely leads to transmission to the unborn child.

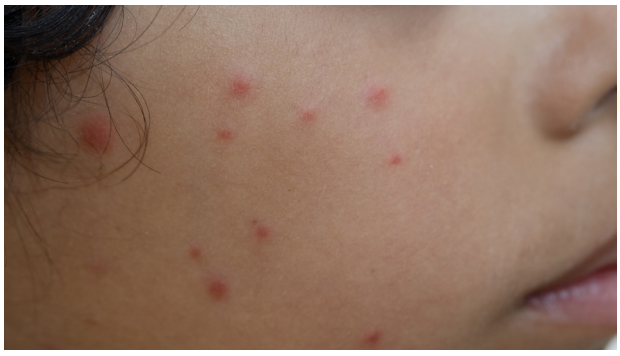
As the rubella infection appears, specific antibodies are generated approximately one week after the viremic stage of infection subsides. Acute infection induces the production of high levels of specific IgG and IgM antibodies. While the IgM antibodies usually disappear after two months, the IgG antibodies persist for a long time, usually for a lifetime. A significant increase in the levels of IgG antibodies occurs even after vaccination, although titres of these antibodies are generally lower than after their natural infection.

Rubella

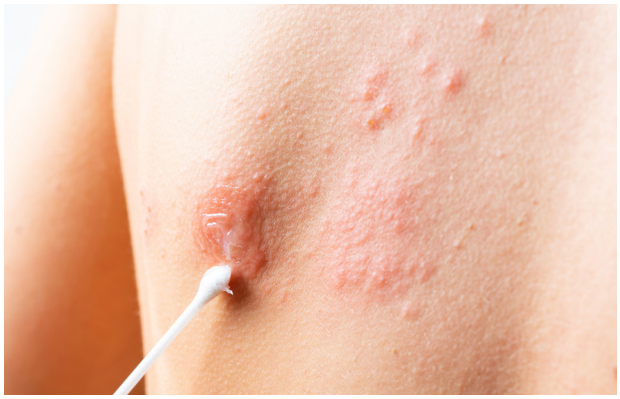
Varicella zoster virus (VZV, HHV-3) belongs to the Herpetoviridae family. The virus causes chicken-pox, varicella (primary infection) and shingles, herpes zoster (reactivation).

Primary VZV infection occurs mainly in childhood and it is transmitted by means of droplet infection. Up to 90% of humans without specific antibodies can be infected during close contact with an infected person. The symptoms include fever, malaise and skin itching preceding the development of characteristic exanthema. The disease usually terminates without any lasting effects. Primary infection in adolescents and adults can be generally more severe with serious complications (e.g. encephalitis, pneumonia and hepatitis) especially in immunocompromised patients. The virus can be transmitted via placenta to the foetus; this can lead to severe congenital defects. Maternal infection of a seronegative female (i.e. without specific antibodies) in late gestation presents serious risk for a newborn.

As a member of the Herpetoviridae family, the virus may persist latently in the organism and can be reactivated subsequently (reduced immunity) producing a disease known as shingles.



Chickenpox



Shingles

Diagnosis of Infection

Diagnosis of the disease is based on clinical manifestation, epidemiological anamnesis and laboratory tests. Laboratory diagnostics is carried out using direct determination of an infectious agent or by determination of specific antibodies by the ELISA method.

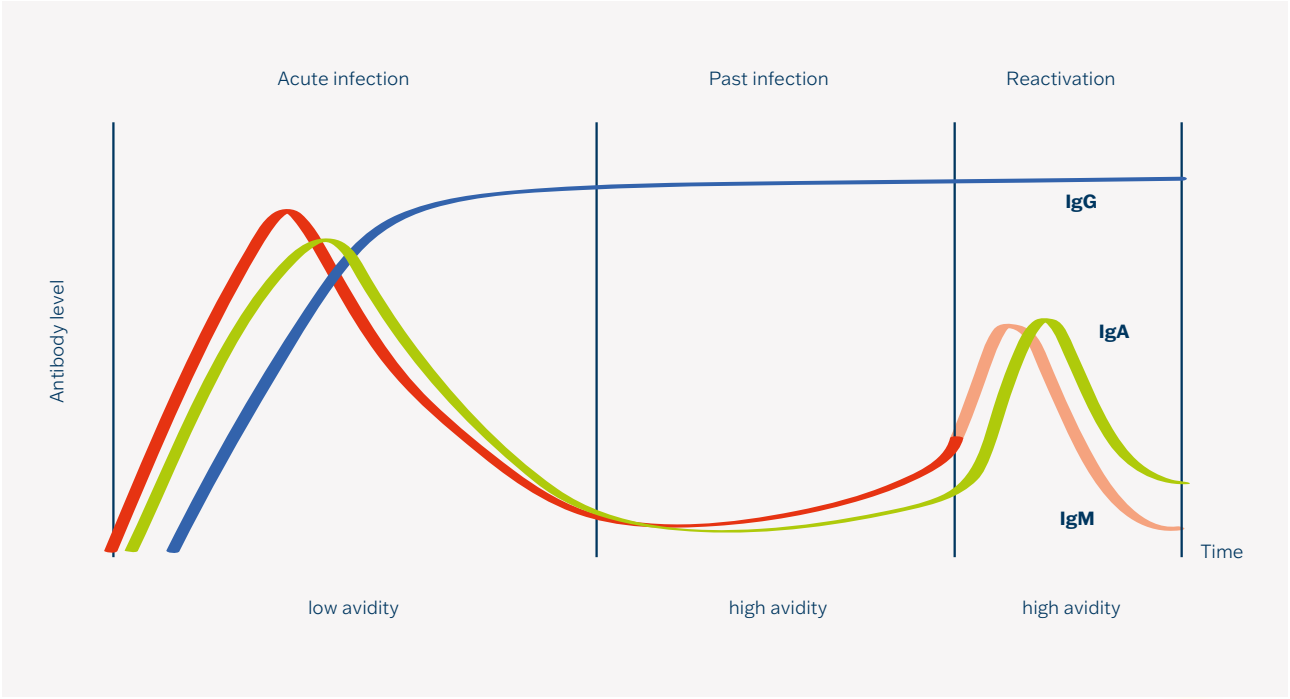
Diagnostic significance of specific antibodies:

IgA, IgM: Antibodies of IgM and IgA class are a sign of an active infection (primary infection and reactivation) and disappear during convalescence. In some cases they can persist for several months.

IgG: Specific IgG antibodies are anamnestic, providing long term protection. Measurement of specific IgG antibodies is useful for assigning patient immunological status. Specific IgG antibodies typically remain at low levels throughout the entire life of the infected person. The method of IgG avidity detection is used for discrimination between primary infection and past infection or reactivation.

Vaccination provides significant increase of IgG antibodies, however the levels of these antibodies in general are lower than after natural infection and may not persist for life.

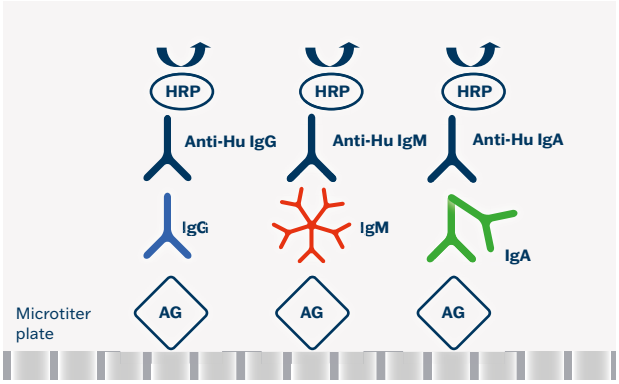
Antibody response



ELISA

Test principle

The assays are based on a sandwich type ELISA method.



Summary protocol

Step		Test steps
	1.	Dilute samples – serum/plasma 1:101 (10 µl + 1 ml) – cerebrospinal fluid 1:3 (50 µl + 100 µl)
	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

Measles

Purified and inactivated native antigen with high content of specific immunodominant epitopes.

Mumps

Purified and inactivated native antigen with high content of specific immunodominant epitopes.

Parvovirus B19

VP2 recombinant protein

Rubella

Purifikovaný a inaktivovaný antigen z kmene HPV-77 s vysokým obsahem specifických imunodominantních epitopů

Varicella zoster virus

Purified and inactivated native VZV antigen with high content of specific immunodominant epitopes.

Clinical application

- Screening test for the detection of specific IgA, IgG and IgM antibodies in human serum or plasma
- Semiquantitative evaluation is suitable for therapy success monitoring
- Disease stage diagnosis
- Diferential diagnostics of viral exanthems
- Diagnostics of pregnant woman and congenitally infected newborns

User comfort

- Komponenty v pracovním ředění
- Barevně odlišené reagencie
- Zaměnitelnost komponent
- Barevně značené stripy s odlamovacími jamkami
- CUT-OFF kontrola a kalibrátory
- Semikvantitativní hodnocení výsledků (Index pozitivity-IP) nebo kvantitativní hodnocení výsledků (IU/ml)
- Quantitative evaluation in international units based on international WHO standard

Advantages

- High diagnostic specificity and sensitivity
- High reproducibility
- High dynamics of antibody response
- Identical assay procedure
- Short total assay time
- Sample diluent with RF-sorbent (EIA IgM)
- Avidity test (EIA Measles IgG, EIA Rubella IgG, EIA VZV IgG)
- Determination of specific antiubodies in cerebrospinal fluid (EIA VZV)
- Ready for automation
- Customer support

EIA kit

SmartEIA kit

Test characteristics

ELISA	Diagnostic sensitivity	Diagnostic specificity
EIA Measles IgG	99.2%	97.8%
EIA Measles IgM	97.7%	99.2%
EIA Mumps IgA	84.0%	99.9%
EIA Mumps IgG	98.7%	95.7%
EIA Mumps IgM	87.5%	99.0%
EIA Parvovirus IgG	98.6%	99.9%
EIA Parvovirus IgM	96.8%	99.9%
EIA Rubella IgG	97.7%	97.3%
EIA Rubella IgM	95.1%	99.6%
EIA VZV IgA	99.9%	99.9%
EIA VZV IgG	98.9%	99.9%
EIA VZV IgM	99.9%	98.9%

Ordering Information

ELISA

Cat. No.	Product	No. of Tests
MeG096	EIA Measles IgG	96
MeM096	EIA Measles IgM	96
SK-MeG096	SmartEIA Measles IgG	96
SK-MeM096	SmartEIA Measles IgM	96
MuA096	EIA Mumps IgA	96
MuG096	EIA Mumps IgG	96
MuM096	EIA Mumps IgM	96
SK-MuA096	SmartEIA Mumps IgA	96
SK-MuG096	SmartEIA Mumps IgG	96
SK-MuM096	SmartEIA Mumps IgM	96
PVG096	EIA Parvovirus B19 IgG	96
PVM096	EIA Parvovirus B19 IgM	96
SK-PVG096	SmartEIA Parvovirus B19 IgG	96
SK-PVM096	SmartEIA Parvovirus B19 IgM	96
RubG96	EIA Rubella IgG	96
RubM96	EIA Rubella IgM	96
SK-RubG96	SmartEIA Rubella IgG	96
SK-RubM96	SmartEIA Rubella IgM	96
VZVA96	EIA VZV IgA	96
VZVG96	EIA VZV IgG	96
VZVM96	EIA VZV IgM	96
SK-VZVA96	SmartEIA VZV IgA	96
SK-VZVG96	SmartEIA VZV IgG	96
SK-VZVM96	SmartEIA VZV IgM	96

SmartEIA kits are designed for automated processing using the Agility® analyzer.

TestLine®

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V09/2022