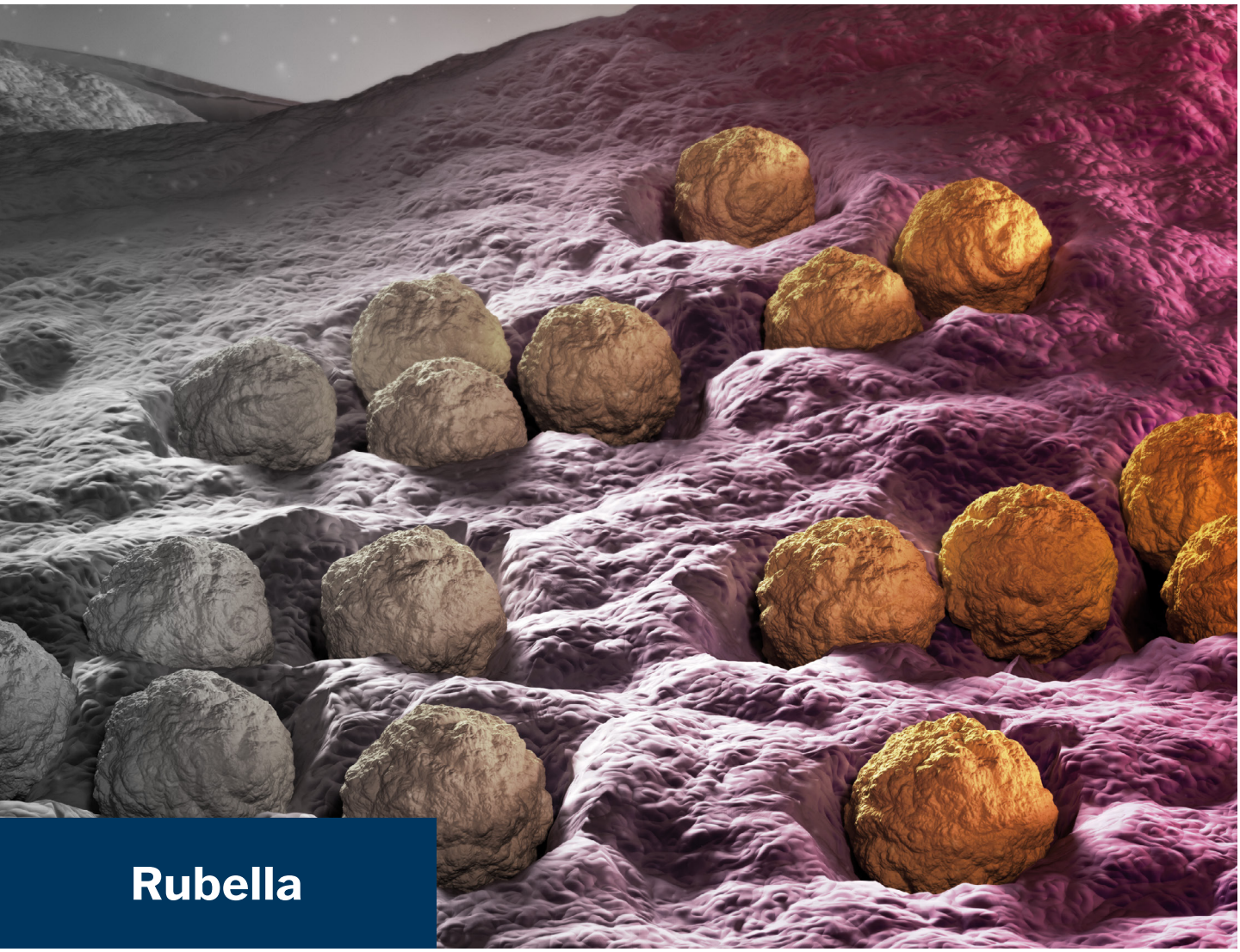


Rubella

Enzyme immunoassay for the diagnosis of Rubella

ELISA kits are optimized and validated for detection of IgG (including avidity) and IgM antibodies in human serum and plasma

IVD CE 2265

Diagnostic kits are intended for professional use in the laboratory.

BG TestLine®

Introduction

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.

Diagnosis of Infection

Diagnosis of the disease is based on clinical manifestation, epidemiological anamnesis and laboratory tests. The most widespread serological method used for the detection of specific IgM and IgG (avidity) antibodies to Rubella in laboratory diagnosis of the infection is ELISA.

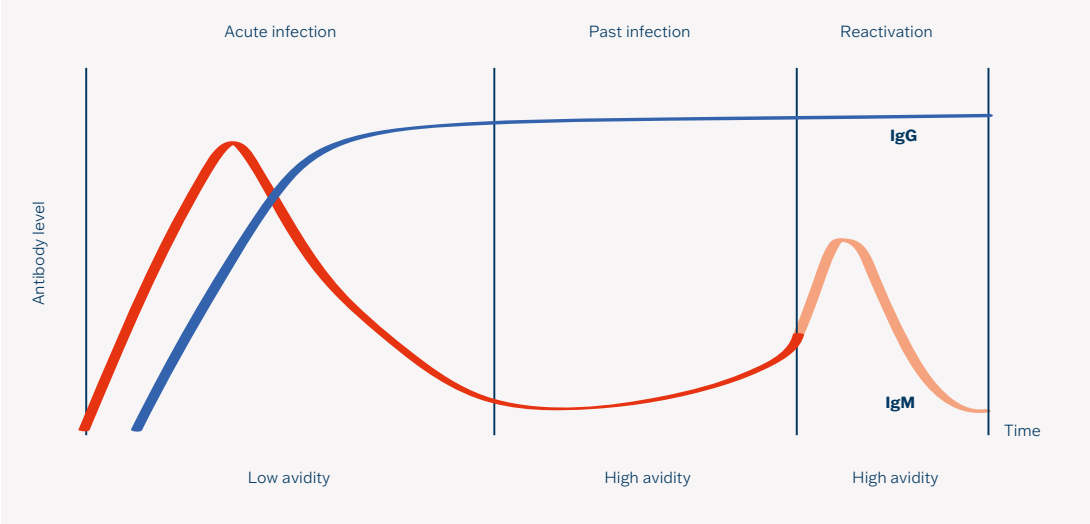
IgM: Antibodies of IgM class are a sign of an active infection (primary infection and reactivation) and disappear during convalescence. In some cases they can persist for several months.

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.

Antigens

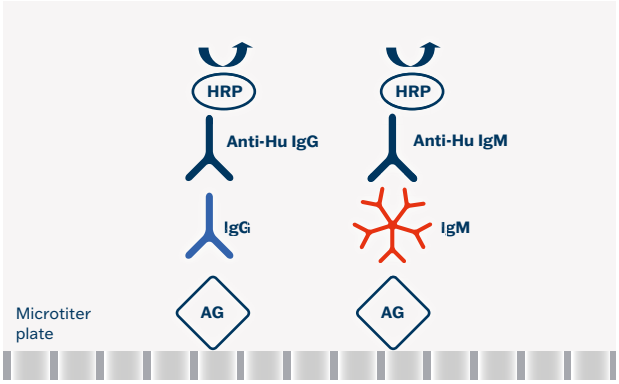
Purified and inactivated antigen from HPV-77 strain with high amount of specific immunodominant epitopes

Antibody Response



Test Principle

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



Protocol Summary

Step		Test steps
	1.	Dilution of samples – serum/plasma 1:101 (10 µl + 1 ml)
	2.	Pipette Controls and diluted samples 100 µl – Including blank
	3.	Incubate 30 min. at 37 °C
	4.	Aspirate and wash the wells 5 times
	5.	Add Conjugate 100 µl – Including blank
	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 15 min. at 37 °C
	10.	Add 100 µl Stopping solution – Including blank
	11.	Read colour intensity at 450 nm

Clinical Application

- Screening test for the detection of specific IgG and IgM antibodies in human serum and plasma
- Differential diagnosis of exanthematous diseases
- Diagnosis of pregnant women and congenitally infected newborns

User Comfort

- Ready-to-use components
- Colour-coded components
- Interchangeable components
- Breakable colour-coded microplate strips CUT-OFF and calibrators included
- Semiquantitative evaluation of results (Index of Positivity) or quantitative evaluation of results (IU/ml)
- Easy assay procedure

Advantages

- Identical assay procedure
- High diagnostic specificity and sensitivity
- High reproducibility
- High dynamics of antibody response
- Short total assay time
- Avidity test (EIA Rubella IgG)
- Sample diluent with RF-sorbent (EIA Rubella IgM)
- The quantitative evaluation in International units was derived from the WHO International Standard (RUBI-1-94)
- Ready for automation
- Customer support

Test Characteristics

ELISA	Diagnostic Sensitivity	Diagnostic Specificity
EIA Rubella IgG	98.1%	97.3%
EIA Rubella IgM	95.1%	99.6%

Ordering Information

ELISA

Cat. No	Product	No. of Tests
RubG96	EIA Rubella IgG	96
RubM96	EIA Rubella IgM	96
SK-RubG96	SmartEIA Rubella IgG	96
SK-RubM96	SmartEIA Rubella IgM	96

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

TestLine®

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