

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 |

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

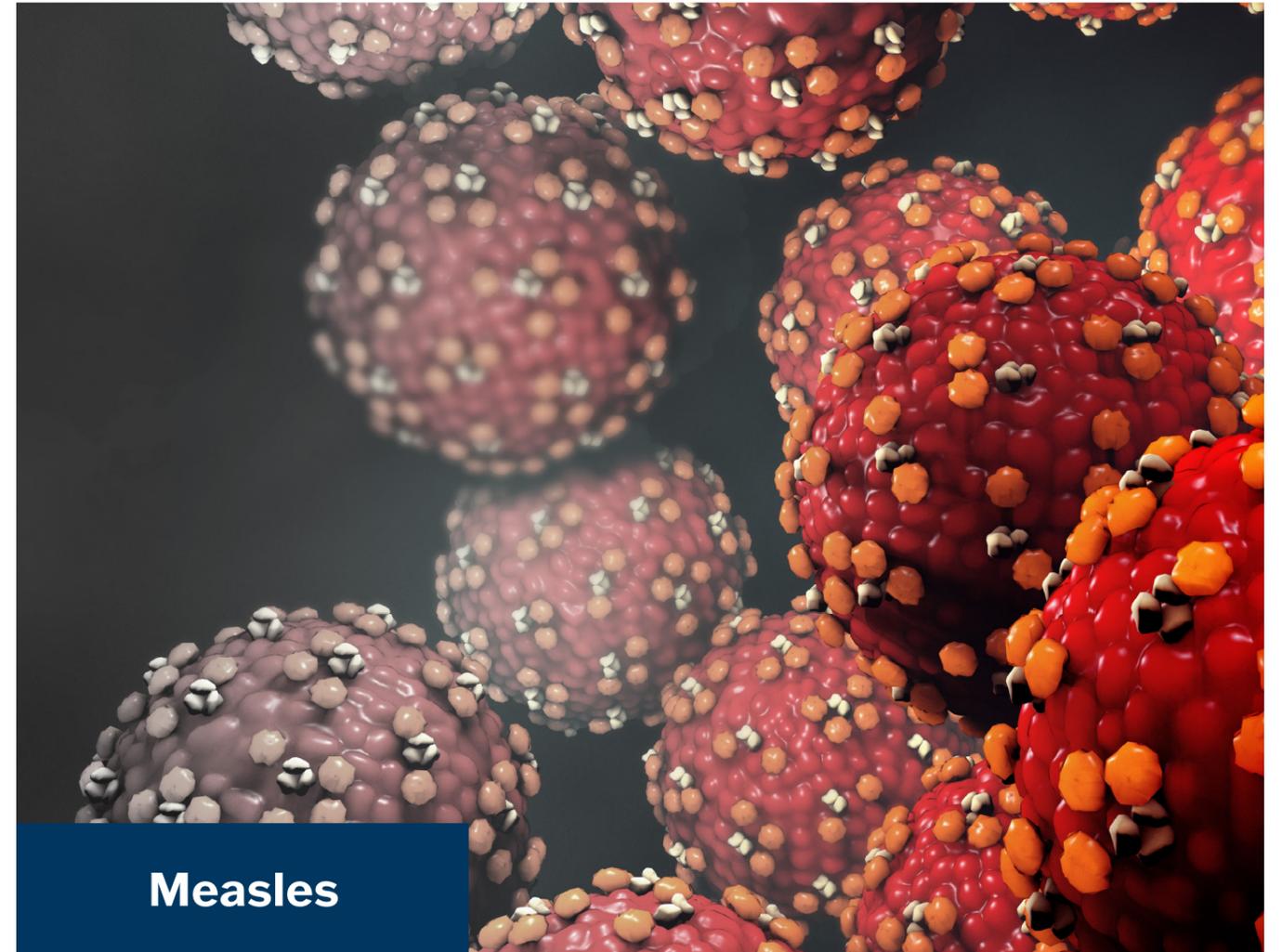


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Company is certified to the quality management system standards ISO 9001 and ISO 13485 for in vitro diagnostics.



Measles

Enzyme immunoassays for the diagnostics of Measles

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



Diagnostic kits are intended for professional use in the laboratory.



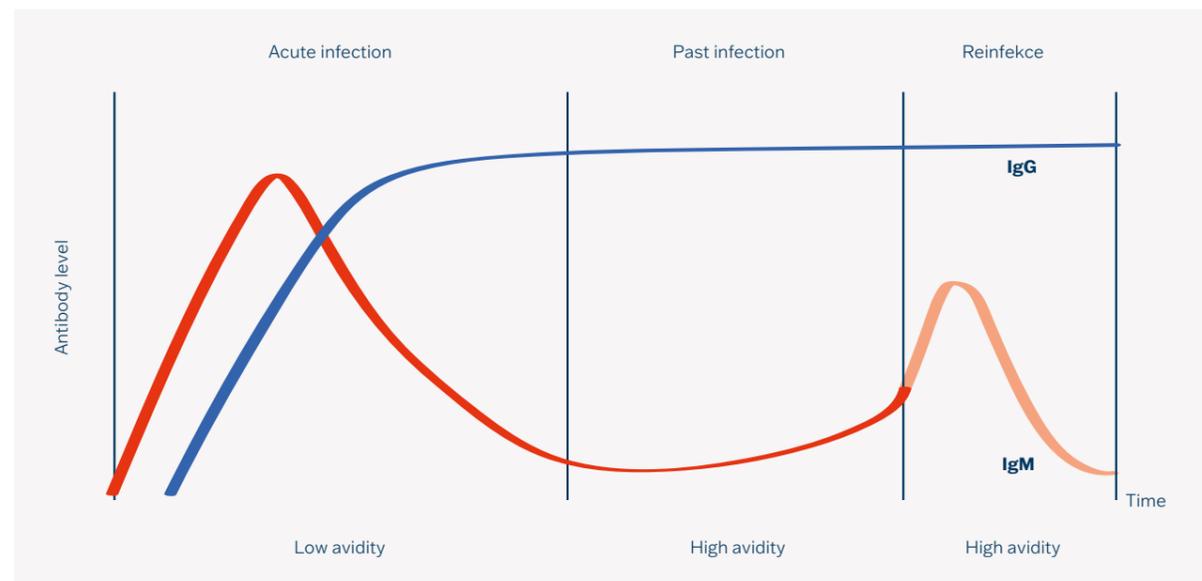
Introduction

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.

Antibody Response



Diagnosis of Infection

Diagnosis of measles is based on clinical picture and laboratory tests. Serological methods testing for specific antibodies using ELISA are often used in laboratory diagnostics of measles.

Specific antibodies are produced within 3–10 days after the onset of clinical signs in measles infection and are typical of IgM and IgG specific antibodies. While IgM antibodies disappear after a few weeks, IgG antibodies persist for a long time, usually for life.

Significant increases in IgG antibody levels occur after vaccination, although titres of these antibodies are generally lower than after natural infection and may not persist for life. The determination of IgG antibody levels also serves as a control of vaccination effect.

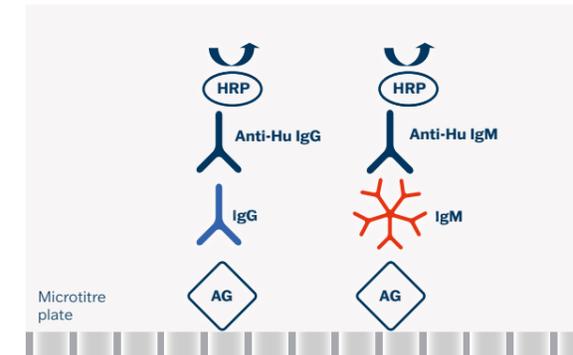
Correlation Method

| EIA Measles TestLine – Conformity in % | IgG | IgM |
|--|------------|------------|
| EIA (competition 1) | 100.0 | 98.9 |
| EIA (competition 2) | 97.6 | 98.9 |
| EIA (competition 3) | 95.9 | 72.5 |

Note: Inconclusive results were excluded from evaluation.

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 |

Antigens

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

Clinical Application

- Screening test for the detection of specific IgG and IgM antibodies in human serum or plasma
- Disease stage diagnosis
- Differential diagnosis of exanthematous diseases

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)

Advantages

- High diagnostic specificity and sensitivity
- High reproducibility
- High dynamics of antibody response
- Identical assay procedure
- Short total assay time
- Quantitative evaluation in international units according to WHO standards (3rd IS 97/648)
- Avidity test (EIA Measles IgG)
- Sample diluent with RF-sorbent (EIA Measles IgM)
- Ready for automation
- Customer support

Test Characteristics

| ELISA | Diagnostic Sensitivity | Diagnostic Specificity |
|-----------------|-------------------------------|-------------------------------|
| EIA Measles IgG | 99.2% | 97.8% |
| EIA Measles IgM | 97.7% | 99.2% |