



SERION ELISA *classic*

Zika Virus IgG/IgM

Intended Use

- Qualitative and quantitative detection of human antibodies in serum or plasma directed against Zika viruses
- Diagnosis of Zika virus infections and epidemiological studies

Diagnostic Efficiency

The evaluation of SERION ELISA *classic* Zika Virus IgG and IgM was performed in an internal study with 80 serum samples from patients with suspected Zika Virus infection as well as with over 100 samples obtained from healthy blood donors in southern Germany, against the ELISA test of another manufacturer. Borderline results have not been included in the calculation.

| Product | Sensitivity | Specificity |
|--|-------------|-------------|
| SERION ELISA <i>classic</i> Zika Virus IgG | 98.6 % | >99 % |
| SERION ELISA <i>classic</i> Zika Virus IgM | 96.6 % | 99.0 % |

Precision

SERION ELISA *classic* Zika Virus IgG

| Sample | Mean value (OD) | Intraassay CV (%) | Mean value (OD) | Interassay CV (%) |
|---------|-----------------|-------------------|-----------------|-------------------|
| Serum 1 | 0.879 | 1.5 | 0.847 | 4.7 |
| Serum 2 | 0.564 | 3.0 | 0.551 | 5.1 |
| Serum 3 | 1.159 | 1.2 | 1.189 | 4.4 |

SERION ELISA *classic* Zika Virus IgM

| Sample | Mean value (OD) | Intraassay CV (%) | Mean value (OD) | Interassay CV (%) |
|---------|-----------------|-------------------|-----------------|-------------------|
| Serum 1 | 1.099 | 3.1 | 1.163 | 3.2 |
| Serum 2 | 0.479 | 1.5 | 0.496 | 3.2 |
| Serum 3 | 0.621 | 2.0 | 0.671 | 3.2 |

Cross Reactivity

| Positive IgG sera | Positive in SERION Zika Virus IgG ELISA |
|-------------------|---|
| TBE Virus | 0/10 |
| Dengue Virus | 4/10* |
| West Nile Virus | 0/10 |

* The observed positive reactions in Dengue virus IgG positive samples can be due to seroprevalence. All positive reactions have been confirmed by positive results in a reference assay as well.

Pathogen

The single-stranded RNA Zika Virus is a member of the family *Flaviviridae*. Two lineages of the Zika virus have been identified which comprise the African lineage and the Asian lineage. The genome consists of approximately 11 kb and encodes three structural (C, prM and E) and seven non-structural (NS1, NS2a, NS2b, NS3, NS4a, NS4b and NS5) proteins.

Disease

Zika virus disease is caused by the Zika virus which is primarily transmitted by mosquitoes of the genus *Aedes* and mainly *Aedes aegypti*. Further, prenatal transmissions of the virus from pregnant women to the fetus, transmissions by sexual intercourse and blood transfusion are of high importance. The WHO estimates up to 4 million Zika virus infections in North-, Central- and South-America during the year 2016. It is estimated that up to 2.17 billion people live in areas prone to Zika virus transmission. Zika virus was first identified in 1947 in a rhesus macaque in the Zika forest in Uganda. A first major outbreak was described in 2007 in Micronesia.

The incubation period is 3-12 days. In approximately 80% Zika virus infections remain asymptomatic. If symptoms occur, the disease (Zika fever) is similar to Dengue fever, but with a milder course and can include fever, maculopapular rash, headache, arthralgia, myalgia and conjunctivitis. Further, it has been observed that a Zika virus infection can cause an increased risk for developing a Guillain-Barré-Syndrom (GBS). In case of

| Positive IgM sera | Positive in SERION Zika Virus IgM ELISA |
|-------------------|---|
| TBE Virus | 0/10 |
| Dengue Virus | 0/10 |
| West Nile Virus | 0/10 |

infections of pregnant women the virus can be transmitted to the unborn child and the fetal infection can correlate with malformations. Symptoms with congenital infections also comprise a reduced growth, microcephaly, neurological symptoms and CNS lesions as well as fetal loss. The risk of fetal malformation seems higher if the infection of the mother occurred in the first trimester.

Diagnosis

The direct pathogen detection via reverse transcriptase (RT) PCR is recommended during the first seven days of symptom onset. Approximately 7 days after onset of symptoms viremia decreases rapidly. In consequence a negative PCR result should be interpreted with caution and does not exclude an infection. Thereafter, serology is the preferred method with a focus on detection of IgM antibodies. Zika virus specific IgM antibodies can be detected 1 week after onset of symptoms and persist for approximately 2-12 weeks. Wherever possible paired serum samples should be collected. Rise of Zika virus specific IgG antibodies is delayed by a few days compared to IgM antibodies and are believed to persist lifelong. Due to the high similarities of antigens between the *flaviviridae* (e.g. West Nile Virus, Dengue Virus, Yellow fever), cross reactivities have to be considered. As similar symptoms are shared between the infections of flaviviruses the interpretation of serological results should also take into account an intensive anamnesis including past journeys, infections and vaccinations.

Highlights

- Usage of recombinant NS1 proteins as antigen to allow reduced cross reactivities also on the background of existing antibodies against other flaviviruses.
- Excellent diagnostic efficiency with high sensitivity and specificity
- High precision and linearity in the measurement range

| Product | Order No. |
|--|-----------|
| SERION ELISA <i>classic</i> Zika Virus IgG | ESR149G |
| SERION ELISA <i>classic</i> Zika Virus IgM | ESR149M |

SERION ELISA control

Please visit our website for more information.

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