



SERION ELISA *classic*

# Dengue Virus IgG/IgM

## Intended use

- Qualitative and quantitative detection of human IgG and IgM antibodies in serum or plasma directed against Dengue Viruses DEN1-4
- Support in the diagnosis of Dengue Virus infections
- Epidemiological studies.

## Diagnostic Efficiency

The evaluation of SERION ELISA *classic* Dengue Virus IgG and IgM tests was performed in an internal study with more than 500 serum samples from patients from Middle America and India with suspected Dengue Virus infection as well as over 100 samples obtained from healthy blood donors in southern Germany, against the ELISA of a leading manufacturer.

| Product                                      | Sensitivity | Specificity |
|--|-------------|-------------|
| SERION ELISA <i>classic</i> Dengue Virus IgG | 96.7 %      | 99.0 %      |
| SERION ELISA <i>classic</i> Dengue Virus IgM | 96.2 %      | >99.0 %     |

## Precision

### SERION ELISA *classic* Dengue Virus IgG

| Sample  | Mean value (OD) | Intraassay CV (%) (n=20) | Mean value (OD) | Interassay CV (%) (n=10) |
|---------|-----------------|--------------------------|-----------------|--------------------------|
| Serum 1 | 1.548           | 1.5                      | 1.633           | 5.0                      |
| Serum 2 | 0.897           | 1.4                      | 0.962           | 5.9                      |
| Serum 3 | 0.639           | 1.3                      | 0.687           | 7.8                      |

## SERION ELISA *classic* Dengue Virus IgM

| Sample  | Mean value (OD) | Intraassay CV (%) (n=20) | Mean value (OD) | Interassay CV (%) (n=10) |
|---------|-----------------|--------------------------|-----------------|--------------------------|
| Serum 1 | 1.136           | 1.9                      | 1.158           | 5.2                      |
| Serum 2 | 0.812           | 3.1                      | 0.830           | 7.7                      |
| Serum 3 | 0.622           | 6.8                      | 0.596           | 5.8                      |

### Pathogen

Dengue Virus is transferred to humans by mosquitos. Approximately 2.5 billion individuals reside in Dengue endemic risk areas. According to the World Health Organization (WHO), up to 100 million cases of Dengue Fever occur worldwide each year. The single-stranded RNA Dengue Virus is a member of the family *Flaviviridae*. Dengue Viruses can be classified into four different serovars namely DEN-1, DEN-2, DEN-3 and DEN-4.

### Disease

The incubation period for Dengue Fever is four to six days. The classical course of an infection is characterized by fever, headache, myalgia, arthralgia and a typical rash. All four serovars induce a serovar-specific not crossprotective long-term immunity. During secondary infections, additional symptoms such as bleedings and shock are frequently observed. It is assumed that Dengue Hemorrhagic Fever (DHF) may result from follow up infections

caused by heterologous Dengue Virus serovars via antibody dependent enhancement. Annually, 250,000 to 500,000 cases of DHF are recorded with between 2 % and 5 % taking a fatal course. If a clinical diagnosis is made early, a health care provider can effectively treat DHF using fluid replacement therapy.

### Diagnosis

Between day 1 to 5 post onset of symptoms NS1 antigen detection as well as PCR are the most reliable methods to identify a Dengue Virus infection. Subsequently, serology is the method of choice for laboratory diagnostics. According to the Pan American Health Organization (PAHO) guidelines 80 % of all Dengue fever cases develop IgM antibodies by day 5 of illness, and 93% – 99 % have detectable IgM antibodies by day 6 post onset of symptoms, which may then remain detectable for more than 90 days. IgG antibodies are detectable at the end of the first week of illness and persist several months or even lifelong.

## Highlights

- Use of a DEN-2 Virus preparation for sensitive demonstration of IgM antibodies directed against all 4 serovars for early detection of acute Dengue Virus infections
- Use of a recombinant multi-epitope antigen of B domains of Dengue Virus serotypes 1-4 for the specific detection of IgG antibodies
- Reduced cross-reactivity with IgG antibodies directed against other *Flaviviruses*,

| Product                                      | Order No. |
|--|-----------|
| SERION ELISA <i>classic</i> Dengue Virus IgG | ESR114G   |
| SERION ELISA <i>classic</i> Dengue Virus IgM | ESR114M   |

### SERION ELISA *control*

Please visit our website for more information.