SERION ELISA *classic*

Dengue Virus IgG/IgM
Dengue Virus superior IgM

Intended use

· Qualitative and quantitative detection of human IgG and IgM anti-
bodies in serum or plasma directed against Dengue Viruses DEN1-4

· Support in the diagnosis of Dengue Virus infections

· Use of the SERION ELISA *classic* Dengue Virus superior IgM,
especially in regions with high prevalence of flaviviruses

· Epidemiological studies

Diagnostic Efficiency

The evaluation of SERION ELISA *classic* Dengue Virus IgG/IgM as well
as Dengue Virus superior 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 or 243
serum samples from patients from Colombia (Dengue Virus superior
IgM) as well as over 100 or 55 (Dengue Virus superior IgM) samples
obtained from healthy blood donors in southern Germany, against
the ELISA of a leading manufacturer.

Product	Sensitivity	Specificity
SERION ELISA *classic* Dengue Virus IgG	96.7 %	99.0 %
SERION ELISA *classic* Dengue Virus IgM	96.2 %	99.3 %
SERION ELISA *classic* Dengue Virus superior IgM	91.5%	>99.0 %

To further analyze the specificity of the IgM tests, a total of 139 clinically negative sera collected in regions where other flaviviruses
are endemic were determined using either SERION ELISA *classic* Dengue Virus IgM, Dengue Virus IgM or a reference ELISA.

	Specificity against clinical symptoms (negative)
SERION ELISA *classic* Dengue Virus superior IgM	93.8 %
SERION ELISA *classic* Dengue Virus IgM	84.0 %
Reference ELISA	88.0 %

Therefore the use of the SERION ELISA *classic* Dengue Virus superior IgM is recommended for regions where other flaviviruses are endemic
and a high demand on the specificity of the test system exists.

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Your Partner in Infectious Serology

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

SERION ELISA *classic* Dengue Virus superior IgM

Sample	Mean value (OD)	Intraassay CV (%) (n=20)	Mean value (OD)	Interassay CV (%) (n=10)
Serum 1	2.698	2.2	2.652	1.6
Serum 2	0.477	2.8	0.415	3.6
Serum 3	0.265	2.4	0.237	3.4

Pathogen

Dengue Virus is transferred to humans by mosquitos. Approximately 3.9 billion individuals reside in Dengue endemic risk areas. According to the World Health Organization (WHO), up to 390 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 serotypes induce a serotype-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 serotypes via antibody dependent enhancement. Overall, about 2 % - 5 % of the reported DHF cases are fatal. 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

· Sensitive demonstration of IgM antibodies for early detection of acute infections

· Use of a stringent dilution buffer included in the SERION ELISA *classic* Dengue Virus superior IgM kit for excellent specificity in regions with high prevalence of flaviviruses

· Specific detection of IgG antibodies for the diagnosis of Dengue Virus infections and epidemiological studies

· Reduced cross-reactivity with IgG antibodies directed against other Flaviviruses, such as TBE or West Nile Virus

Product	Order No.
SERION ELISA *classic* Dengue Virus IgG	ESR114G
SERION ELISA *classic* Dengue Virus IgM	ESR114M
SERION ELISA *classic* Dengue Virus superior IgM	ESR1141M

SERION ELISA *control*
Please visit our website for more information.

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