**Anti-Dengue virus IIFT**

**Indications:** Test system for the in vitro determination of antibodies against Dengue virus in human serum or plasma for the diagnosis of the following diseases: classic Dengue fever, Dengue haemorrhagic fever, Dengue shock syndrome.

**Clinical significance:** Dengue viruses belong to the flavivirus family (other known representatives of this group are yellow fever virus, West Nile virus and TBE virus). Dengue fever is the most common vector transmitted virus infection in humans. Four different Dengue serotypes exist (DENV1 to DENV4). The vector is a mosquito of the Aedes species (A. aegypti, A. albopictus), which can be found worldwide in tropical and subtropical regions. In Germany, up to 1,000 cases of imported Dengue fever are reported every year.

After a mosquito bite the disease manifests itself through flu-like symptoms after an incubation period of 2 to 7 days. The classic Dengue fever is a self-limiting, short-term disease which is accompanied by high fever of over 40°C, severe headache, muscle and joint pains, exanthema and lymph node swellings. Complications are known to be severe cases of e.g. Dengue haemorrhagic fever (DHF) or Dengue shock syndrome (DSS). DHF expresses itself in the form of distinct haemorrhagic symptoms such as petechiae, black and tar-like stool, nose and skin bleeds. Complications such as circulatory disturbances and even shock can occur. Whereas primary infections are often mild, the risk of haemorrhagic fever significantly increases after a secondary infection with a heterologic serotype. Lethality of the DHF amounts to 6 – 30%.

**Relevance of serological diagnostics:** Dengue fever should always be differentially diagnosed from other tropical diseases such as malaria, yellow fever, chikungunya fever, typhus abdomenals and other bacteraemia due to its mainly unspecific symptoms. The infectious agent can only be detected within the first few days of the disease during a viraemic phase using RT-PCR or performing an in vitro cultivation of the virus. NS1 (nonstructural protein 1) is an important marker for the detection of an acute dengue infection. NS1 can be detected in the serum of infected patients at the onset of clinical symptoms in both primary and secondary infections (NS1 ELISA order no. EQ 266a-9601-1). Antibodies can be detected after approximately the fifth day of illness. The symptoms and the resulting medical examination occur with a delay, therefore the serological detection of antibodies against Dengue virus plays a significant role in the diagnosis of the disease, as the virus itself can only be detected for approximately 10 days. After a secondary infection with a heterologous serotype the IgG antibody titer increases up to tenfold. Cross reactions with other flaviviruses must be taken into account.

**Software/Automation:**
- **EUROLab II Plus**
- **EUROLiquidHandler**
- **Sprinter XL**

* Currently not available as IVD in the EU.

**Muds in Germany**
Test characteristics

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Test principle: The indirect immunofluorescence test is an in vitro assay for the determination of specific antibodies against Dengue viruses. Four BIOCHIPS coated with infected cells (Dengue virus types 1, 2, 3 and 4) are fixed on each test field of a slide. With this EUROIMMUN BIOCHIP Mosaic, four substrates can be positioned next to each other on one reaction field and incubated simultaneously with one dilution serum, allowing a detailed patient antibody profile which can be established with a single test.

Test procedure: EUROIMMUN BIOCHIP slides are incubated using the proprietary TITERPLANE™ Technique, enabling multiple samples to be incubated next to each other and simultaneously under identical conditions. Results are evaluated by fluorescence microscopy. Incubation of the substrates with the positive and negative controls provided in each kit verifies correct performance of the test and aids evaluation.

Evaluation data: A mixed panel was investigated, consisting of 110 (IgG) and 99 (IgM) precharacterised patient sera (Robert Koch Institute Berlin/ Germany, Berhard Nocht Institute Hamburg/ Germany, University of Jeddah/ Saudi Arabia) and 200 (IgG) and 150 (IgM) sera of healthy blood donors with negative expectation value (University clinical centre Schleswig-Holstein, Campus Lubeck/ Germany).

The detection of class IgG and IgM antibodies against Dengue virus (types 1 to 4) using EUROIMMUN IIFT yielded the following results: specificity 96.4% (IgG) and 96.2% (IgM), sensitivity 96.6% (IgG) and 98.5% (IgM).

Technical Data:

Antigen substrate: Dengue virus, types 1, 2, 3, 4
Sample material: Serum or plasma.
Sample dilution: IgG: Qualitative evaluations: 1:100 (quantitative 1:100/1000 etc.)
IgM: Qualitative evaluations: 1:10 (quantitative 1:100/1000 etc.)
Test procedure: 30 min (sample) / 30 min (conjugate). Room temperature.
Microscopy: Objective 20x
Excitation filter: 488nm, colour separator: 510 nm, blocking filter: 520 nm
Light source: EUROIMMUN LED or mercury vapour lamp, 100 W
Reagents: Ready for use, with the exception of the PBS-Tween buffer (for washing steps).
Stability: All kit components are stable for at least 18 months from the date of manufacture.
Kit formats: 10 or 20 slides, each containing 3, 5 or 10 test fields.
Kits include all necessary reagents.
Order no.: Anti-Dengue Virus IIFT Mosaic (Types 1-4) FI 266a-####-G, M

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