Indications: Test system for the in-vitro determination of antibodies against EBV in human serum or plasma for the diagnosis of the following diseases: infectious mononucleosis, Burkitt’s lymphoma, nasopharyngeal carcinoma.

Clinical significance: Epstein-Barr virus (EBV) is the causative agent of infectious mononucleosis, a febrile disease usually accompanied by pharyngitis and lymphadenopathy which is frequently associated with hepatosplenomegaly and rarely with an exanthema. However, EBV infections are also found in connection with Burkitt’s lymphoma and nasopharyngeal carcinoma.

Infectious mononucleosis must be differentiated from cytomegaly and toxoplasmosis and, in the case of atypical progress, also from HIV or other infections. During pregnancy, the Epstein-Barr virus can cause an infection of the placenta resulting in damages of the fetal heart, eyes and liver. EBV-induced kidney infections ranging from microhaematuria to acute kidney failure have been observed in children.

Relevance of serological diagnostics: Infectious mononucleosis can easily be confused clinically with cytomegaly, toxoplasmosis, or hepatitis. Since direct evidence of the virus is difficult to obtain, serological parameters routinely serve as diagnostic markers. Parallel determination of antibodies against EBV-CA, EBV-EA, and EBNA not only allows differentiation between acute and past EBV infections, but can also provide evidence of chronicity or the presence of reactivation. For the determination of antibodies against EBV-CA, EBV-EA, and EBNA, indirect immunofluorescence is considered the gold standard. Serologically difficult patterns, such as persistent anti-EBV-CA IgM antibodies or the absence of specific anti-EBV-CA IgM antibodies in fresh infections, can be clarified by measuring the avidity of anti-EBV-CA IgG antibodies.
**Test Characteristics**

**BIOCHIP Sequence EBV (Avidity test)**

**Test principle:** The indirect immunofluorescence test is an in vitro assay for the determination of specific antibodies against EBV antigens. BIOCHIPs coated with EBV-infected cells are fixed onto the reaction fields of a microscope slide. With EUROIMMUN BIOCHIP Technology, different substrates can be positioned next to each other on one reaction field and incubated simultaneously, allowing a complete antibody profile of up to 10 patients to be established with a single slide.

**Test performance:** EUROIMMUN BIOCHIP slides are incubated using the proprietary TITERPLANE™ Technique. This technique enables multiple samples to be incubated next to each other and simultaneously under identical conditions. Results are evaluated by fluorescence microscopy.

**Sensitivity and specificity:** Patient sera of different international reference centres (INSTAND/Germany, NEQAS/Great Britain and Labquality/Finland) were investigated with the EUROIMMUN BIOCHIP Sequence EBV. Based on the expectation value, the following sensitivity and specificity values were determined:

**Avidity (EBV-CA):** In 129 sera (origin: Germany) antibodies against EBV-CA (IgM), EBNA and EBV-EA (IgG) were determined in addition to the EBV-CA avidity test. Due to the resulting serological pattern, an acute infection could be diagnosed or ruled out for each serum. In general, low-avidity antibodies occur in acute infections, in all other cases high-avidity antibodies are found. The agreement between result and expectation value was 97%.

**Reference range:** The following antibody prevalences (titer 1:10 or higher) were determined for EBV-CA (IgG), EBV-CA (avidity), EBV-CA (IgM), EBV-EA (IgG) and EBNA with sera from healthy blood donors (origin: Germany):

**Technical Data:**

- **Antigen substrate:** EBV-CA expressing cells (P3HR1), EBV-EA expressing cells (EU 33), EBNA expressing cells (Raji)
- **Sample dilution:** Serum or plasma. Qualitative: 1:10, quantitative: 1:10/100/1000 etc. There is no upper limit to the measurement range.
- **Test procedure:** 60 min (sample) / 30 min (PBS-Tween, urea, complement) / 30 min (conjugate). Room temperature.
- **Microscopy:** Objective 20x
  - Excitation filter: 488 nm, 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 dilutions and washing steps) and the complement.
- **Stability:** All kit components are stable for at least 18 months from the date of manufacture.
- **Standard kit formats:** 10 or 20 slides, each containing 1, 2 or 10 sequences. Kits include all necessary reagents.
- **Order no.:** FL 2799-####-1 X
- **Related products:** FL 2791-####-2 A (IIFT Mosaic: Anti-EBV-CA and Anti-EBV-EA, IgA)