

EliSpot and CD57+: Important Diagnostic Tests for Lyme Borreliosis

ELISPOT: ACTUAL ACTIVITY

Lyme Borreliosis does not only show humoral immune responses by antibodies, but can activate T-lymphocytes at the same time. Once *Borrelia burgdorferi* is not active anymore, the T-cellular immune response should cease.

It is not possible to test the treatment success by *Borrelia* antibodies, because the "titer" of antibodies can persist in the blood over years. Recent *Borrelia burgdorferi* infections (e.g. 'bull's-eye rash' or 'summer flu') can develop antibodies after weeks and sometimes do not show them at all.

The *Borrelia* EliSpot can eliminate some problems. The test reflects the actual *Borrelia burgdorferi* activity of chronic and recent *Borrelia burgdorferi* infections. It is highly sensitive and can detect even one single *Borrelia burgdorferi*-reactive T-cell in the sample. With detection levels that can be as low as one cell in 100,000, this test is one of the most sensitive cellular assays available. The EliSpot is between 20 and 200 times more sensitive than a conventional ELISA. It displays a similar sensitivity as a RT-PCR (Real Time PCR) analysis but detects the secreted protein instead of the mRNA (messenger RNA).

The EliSpot can be helpful when monitoring therapies. Results should usually be negative about 4 to 8 weeks after completion of an effective therapy.

The **Enzyme Linked ImmunoSpot** (EliSpot) belongs to the IGRA (Interferon-Gamma-Release Assay) test systems.



The *Borrelia* EliSpot includes the following antigens:

- *Borrelia burgdorferi* complete antigen: an antigen which stimulates the immune response and reacts with products, e.g. antibody of that response, cf. hapten.
Borrelia burgdorferi B31-reference strain (*Borrelia burgdorferi sensu stricto*)
- *Borrelia burgdorferi* Peptide-Mix:
OspA from *Borrelia b. sensu stricto*, *Borrelia afzelii*, *Borrelia garinii* + OspC native + DbpA recombinant
Explanation: Native = cultured antigens / Recombinant: produced with genetic technology
- *Borrelia burgdorferi* LFA-1 (Lymphocyte Function Antigen 1):
Own body protein + *Borrelia burgdorferi sensu stricto* (shared epitope). Often associated with autoimmune diseases: collagenosis, rheumatoid arthritis, vasculitis (ANA, CCP-antibodies, ANCA)

The EliSpot reflects the actual T-cellular activity of Lyme disease:

Indication of an actual active *Borrelia burgdorferi* infection in cases of a positive EliSpot post-treatment.

The T-Cell-Spot/IGRA has been approved for *M. tuberculosis* by the FDA in May 2011:

"... A positive result suggests that an infection is likely, a negative result suggests that an infection is unlikely..." "...Results can be available within 24 hours..."

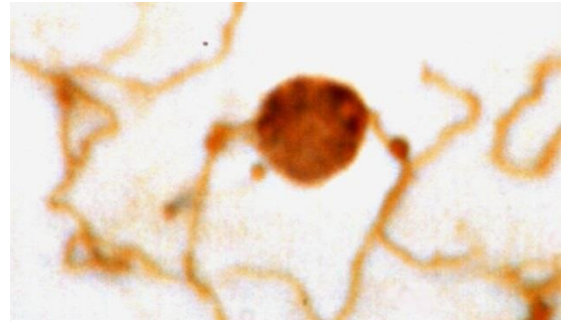
ELISPOT: The new T-Cell Test is a "Game Changer" for Lyme disease

"... The sensitivity of ELISPOT is estimated at 84%, and the specificity is 94%..." "... ELISPOT assays provide robust, highly reproducible data..." "... ELISPOT can be retested for the acquisition of additional information in follow-up assays..." "... the two assays systems (ELISPOT + CD57-cell count) compliment each other in the quest to understand T cell-mediated immunity in vivo...."

(Lehman PV et al.: Unique Strengths of ELISPOT for T Cell Diagnostics. In: Kalyuzhny AE. Handbook of ELISPOT: Methods and Protocols, Methods in Molecular Biology, Vol. 792. 2nd Ed: Springer; 2012: 3-23)

EliSpot (www.elispot.com) is available for:

1. Borrelia burgdorferi
2. Ehrlichia/Anaplasma
3. Chlamydia pneumoniae
4. Chlamydia trachomatis
5. Yersinia species
6. Epstein-Barr-Virus (EBV)
7. Cytomegalo Virus (CMV)
8. Herpes Simplex Virus (HSV) 1/2



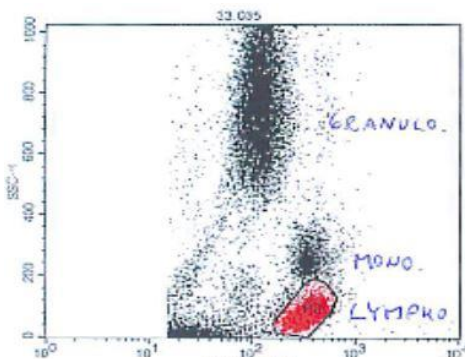
Borrelia Cyst

Material: 3 x 9 ml CPT-tubes (To be kept at room temperature, do not cool or centrifuge!)

Medical indications:

- Diagnosis of chronic Borreliosis in sero-negative or -ambiguous patients with clinical suspicion of Lyme Borreliosis
- Confirmation of Lyme Borreliosis in sero-positive patients lacking clinical suspicion of Lyme Borreliosis
- Identification of patients with chronic infections
- Early confirmation of therapeutic success

CD57+: CHRONIC ACTIVITY



Cell-Differentiation with a Flow Cytometer

The CD57+ cells document the extent of the immune suppression of chronic Lyme disease. Based on the current literature, CD57+ cells provide prognostic laboratory parameters during and after the treatment of chronic Lyme disease.

Clinical research studies and case studies have shown that chronic Lyme infections are often accompanied by changes in the cellular immune defence. Evidence for this is a decreased number of natural killer cells (NK/CD3-CD56+), in particular, a decreased absolute number of activated NK cells (CD3-CD56+CD57+). While acute Borrelia burgdorferi infections and other diseases show normal CD57+ parameters, chronic Lyme patients often have less than 100 CD57+ cells/ μ l.

According to scientific studies, a suppressed absolute number of CD57+ cells has mainly been observed in patients whose nervous system had been affected, rather than in patients whose tissue or skeleton system had been affected. A decrease of CD57+ cells persisted until an improvement in symptoms was achieved with the use antibiotic and other treatment forms. In reverse, a decreased CD57+ parameter is seen as a measurable signal for an active chronic Borrelia infection and can be a possible indicator for a successful therapy.

Material: 1 x 3 ml EDTA-tube, 1 x 6 ml Heparin-tube (Both to be kept at room temperature, do not cool or refrigerate!)

Medical indications:

- Diagnosis of chronic LB
- Decision about the length of therapies
- Confirmation of therapeutic success

If you would like to order our Test-Kits and forms and need more information on shipping and blood taking, please feel free to contact:

info@arminlabs.com

phone: 0049 821 780 931 50

www.arminlabs.com

ArminLabs GmbH - CEO: Armin Schwarzbach MD PhD

Zirbelstraße 58, 2nd floor · 86154 Augsburg · Germany · Phone: 0049 821 780 931 50 www.arminlabs.com

Email: info@arminlabs.com · VATReg-No.: DE815543871 · Amtsgericht Augsburg HRB 29350