



**Reagent**

# Unique diagnostics portfolio for tick-transmitted diseases



## ReaScan+ reader

ReaScan+ reader is a compact rapid test reader with an intuitive graphical user interface. It is fast, reliable, and easy-to-use. The advanced features of the device enable flexible laboratory workflow. You may also use the pre-programmed reading options to optimize usability of the reader. The device is connectable to LIS.



Product	Ref.number
ReaScan+ reader	105100
ReaScan+ connect server	105130
Zebra DS2208 SR USB-Kit Black barcode scanner	105110
Dymo LabelWriter 450 printer	105120

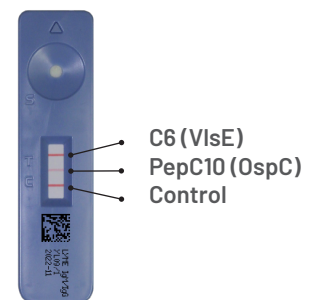
## C6 LYME rapid tests

### ReaScan+ C6 LYME IgG

ReaScan+ C6 LYME IgG is a lateral flow rapid test intended for detection of *Borrelia burgdorferi* specific IgG antibodies in human serum and cerebrospinal fluid (CSF). The result is used as an aid in diagnosis of Lyme Borreliosis (LB).

### ReaScan+ LYME IgM/IgG Combo

ReaScan+ LYME IgM/IgG Combo is a lateral flow rapid test intended for qualitative detection of *Borrelia burgdorferi* specific antibodies in human serum and cerebrospinal fluid (CSF). The test uses C6 (VlsE) and PepC10 (OspC) antigens in separated test lines. PepC10 generates an early IgM response and thus it is likely to react especially in acute Lyme disease.



Product	Test performance	Packaging	Ref. number
ReaScan+ C6 LYME IgG	Specificity 99 % (CSF), 95 % (serum) Sensitivity 97 % (CSF), 97 % (serum)	10 tests	114313
ReaScan+ LYME IgM/IgG Combo	PPA 94,8 % (CSF, serum/ plasma) NPA 95,6 % (CSF, serum/plasma)	10 tests	115103

The diagnostic sensitivity of the ReaScan+ C6 LYME IgG was determined by analyzing 108 paired serum and CSF samples from definite LNB patients. The diagnostic specificity of the ReaScan+ C6 LYME IgG was evaluated by analyzing paired serum and CSF samples from 104 non-LNB patients. EQV results counted as positive.

ReaScan+ LYME IgM/IgG Combo PPA and NPA values for 326 samples including 168 positive serum/plasma samples, 117 negative serum/plasma samples, 23 positive CSF samples and 18 negative CSF samples. EQV ReaScan+ LYME IgM/IgG Combo results were calculated as negatives.

## ReaScan CXCL13

ReaScan CXCL13 is a lateral flow rapid test for semiquantitative determination of CXCL13 in human CSF, which helps clinicians in the treatment decision for suspected Lyme neuroborreliosis (LNB) patients.

Product	Test performance	Packaging	Ref. number
ReaScan CXCL13	Specificity 96 % Sensitivity 100 % with cut-off 250 pg/mL	10 tests	114253

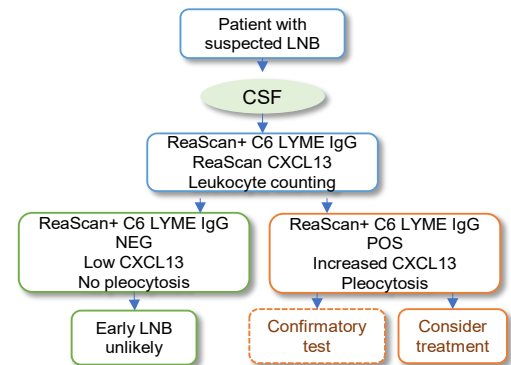
Performance was obtained by comparing ReaScan CXCL13 with a widely used CXCL13 ELISA (Human CXCL13/BLC/BCA-1 Quantikine, R&D Systems, Minneapolis, USA) with 225 patient samples with a suspected diagnosis of LNB. Ref.: Pietikäinen A, et al, Point-of-care testing for CXCL13 in Lyme neuroborreliosis, *Diagn Microbiol Infect Dis* (2018), <https://doi.org/10.1016/j.diagmicrobio.2018.02.013>.

## Lyme borreliosis and neuroborreliosis

Lyme borreliosis, also known as Lyme disease, is a tick-transmitted infectious disease caused by the spirochete *Borrelia burgdorferi sensu lato*. In Europe and Eurasia, the infections are caused by *Borrelia afzelii*, *Borrelia garinii* and *Borrelia burgdorferi sensu stricto*. In North America, *Borrelia burgdorferi sensu stricto* is considered as the primary agent of LB.

The most common initial sign of LB is the skin infection (erythema migrans; EM) at the site of a tick bite. If left untreated, *Borrelia* spirochetes are capable of spreading to multiple tissues and organs leading to disseminated stage manifestations, namely infection of the nervous system (Lyme neuroborreliosis, LNB), infection of the joints (Lyme arthritis), borrelial lymphocytoma, chronic skin disorders (acrodermatitis chronica atrophicans, ACA), and Lyme carditis. There is no effective vaccine currently available to prevent LB, but the most LB and LNB cases can be treated successfully with antibiotics.

### Proposed laboratory diagnostic workflow



## C6 and CXCL13 in diagnostics of Lyme disease

The diagnosis of LB and LNB relies on a combination of clinical and laboratory findings. C6 peptide, derived from the VlsE surface protein of borrelia, is an early-phase IgG antigen. Thus, C6 peptide based serological tests are suitable for the diagnostics of both early and disseminated LB. C6 peptide antigen is highly immunogenic. It is specific for *Borrelia* strains causing Lyme disease, as C6 peptide is not found in other infectious organisms. ReaScan+ C6 LYME IgG test can detect different *B. burgdorferi* species (*Borrelia afzelii*, *Borrelia garinii* and *Borrelia burgdorferi sensu stricto*).

The chemokine CXCL13 has been shown to be elevated in the CSF of patients with early Lyme neuroborreliosis, even before the development of intrathecal antibodies against borrelia. The increase of CXCL13 concentration in CSF during early LNB is significant; the CSF chemokine level in healthy individuals is very low, while in LNB patients CXCL13 concentration is usually more than 100-1000 times higher.

Similar levels of CXCL13 as seen in LNB have been observed e.g. in patients with CNS lymphoma, tuberculous meningitis and neurosyphilis. CXCL13 is considered as an activity marker, as CXCL13 level falls rapidly within a few weeks after the initiation of successful antibiotic therapy.

Ref.: Pietikäinen et al. 2022. Clinical performance and analytical accuracy of a C6 peptide-based point-of-care lateral flow immunoassay in Lyme borreliosis serology, *Diagn Microbiol Inf Dis* 103.

Ref.: Haglund S et al. CXCL13 in laboratory diagnosis of Lyme neuroborreliosis—the performance of the recomBead and ReaScan CXCL13 assays in human cerebrospinal fluid samples. *Eur J Clin Microbiol Infect Dis*. 2021 Oct 9. doi: 10.1007/s10096-021-04350-y.

Ref.: Ziegler et al. Comparative Analysis of the Euroimmun CXCL13 Enzyme-Linked Immunosorbent Assay and the ReaScan Lateral Flow Immunoassay for Diagnosis of Lyme Neuroborreliosis. *J Clin Microbiol*. 2020 Aug 24;58(9):e002707-20.

Ref.: Nigrovic LE et al. 2019. Higher C6 enzyme immunoassay index values correlate with a diagnosis of noncutaneous Lyme disease. *Diagn Microbiol Infect Dis*. Jun;94(2):160-164.

Ref.: Pietikäinen A et al. 2018. Point-of-care testing for CXCL13 in Lyme neuroborreliosis. *Diagn Microbiol Infect Dis*. Jul;91(3):226-228

## ReaScan TBE IgM

ReaScan TBE IgM is a lateral flow rapid test for qualitative detection of tick-borne encephalitis (TBE) virus specific IgM antibodies in human serum and cerebrospinal fluid (CSF).

Product	Test performance	Packaging	Ref. number
ReaScan TBE IgM	Specificity 100 % (CSF), 98% (serum) Sensitivity 92 % (CSF), 99 % (serum)	10 tests	114106

Performance was evaluated with 172 serum samples from earlier diagnosed TBE patients and 141 TBEV IgM negative serum samples. See Albinsson B et al. 2020. Multi-laboratory evaluation of ReaScan TBE IgM rapid test, 2016 to 2017. Euro Surveill. 2020 Mar;25(12).

## Tick-borne Encephalitis (TBE)

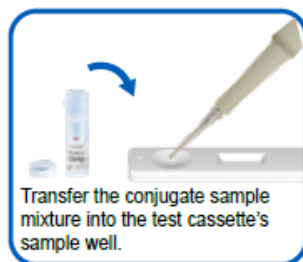
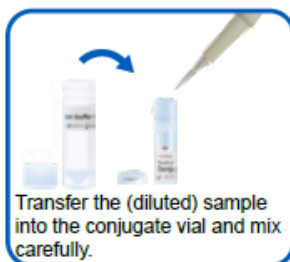
TBE virus belongs to Flaviviruses and it may cause an infection of the central nervous system (CNS). TBE virus, which is found in most European countries, Russia and Northern Asia, can be transmitted to humans by the bite of infected ticks (e.g. Ixodes ricinus, Ixodes persulcatus).

Symptoms of TBE virus infection usually appear in a two-phase course. After an incubation period of 1-2 weeks, flu-like symptoms are developed in the viremic phase of the illness and then a brief symptom-free period occurs.

The second phase of the disease may involve the CNS with symptoms of e.g. meningitis, meningoencephalitis, and meningoencephalomyelitis.

The laboratory diagnosis of TBE is based on the detection of TBE virus specific IgM and IgG antibodies in serum and CSF. Reagent provides ReaScan TBE IgM rapid test for the detection of TBE virus specific IgM antibodies from human serum and CSF.

Ref.: Albinsson B et al. 2020. Multi-laboratory evaluation of ReaScan TBE IgM rapid test, 2016 to 2017. Euro Surveill. 2020 Mar;25(12).



## Reagent C6 LYME IgM/IgG EIA

Reagent C6 LYME IgM/IgG EIA is a qualitative enzyme immunoassay for detection of Borrelia burgdorferi specific IgM and IgG antibodies in human serum and cerebrospinal fluid (CSF). The result is used as an aid in diagnosis of Lyme borreliosis (LB).



Product	Test performance	Packaging	Ref. number
Reagent C6 LYME IgM/IgG EIA	PPA 92,7 % (CSF, serum/plasma) NPA 95,9 % (CSF, serum/plasma)	96 wells	114403

Reagent C6 LYME IgM/IgG EIA PPA and NPA values for a total of 341 samples (291 serum and plasma samples, 50 CSF samples). EQV Reagent C6 LYME IgM/IgG EIA results were calculated as negatives.