



CXCL13 ELISA



- **First commercial CXCL13-ELISA worldwide to be approved for in vitro diagnostics**
- **Helps in diagnosing cases of acute neuroborreliosis**
- **Reliable marker for the disease course after treatment**

Technical data

Coating	Highly purified monoclonal anti-CXCL13 antibody
Calibration	Quantitative, in picogramme per mililiter (pg/ml), 6 calibrators
Evaluation	EUROIMMUN proposes the interpretation of results as follows: Normal range: < 20 pg/ml; exclusion of neuroborreliosis Borderline range: ≥ 20 bis < 30 pg/ml Increased: ≥ 30 bis ≤ 100 pg/ml Strongly increased: > 100 pg/ml; if corresponding symptoms are present, indicator of acute neuroborreliosis
Sample dilution	Liquor; 50 μ l undiluted
Reagents	Ready for use. Exception: wash buffer (10x). Colour-coded solutions
Test procedure	180 min / 30 min / 15 min, room temperature. Fully automatable
Measurement	450 nm. Reference wavelength between 620 nm and 650 nm
Kit format	96 break-off wells, kit includes all necessary reagents
Order number	EQ 6811-9601-L

Clinical significance

The chemotactic cytokine (chemokine) CXCL13 is a cellular messenger which is produced by monocytes, macrophages and dendritic cells. It is an important chemoattractant for lymphocytes in the CSF. The detection of CXCL13 in the CSF is of particular importance in the diagnosis of neuroborreliosis.

Diagnosis of acute neuroborreliosis has up until now been based on the typical clinical picture (meningitis, meningoradiculitis, neurological deficits), the detection of an inflammatory CSF syndrome (for example pleocytosis, blood-CSF barrier dysfunction) and the detection of intrathecal synthesis of Borrelia-specific antibodies. The antibody detection does not, however, provide information on the activity of the infection. Unlike in serum, the detection of IgM in CSF is not an indicator of acute infection. The classic changeover in immunoglobulin classes is also not observed in CSF. Furthermore, persistence of Borrelia-specific IgG and/or IgM antibodies despite suitable therapy hinders the reliable differentiation of past and active infections.

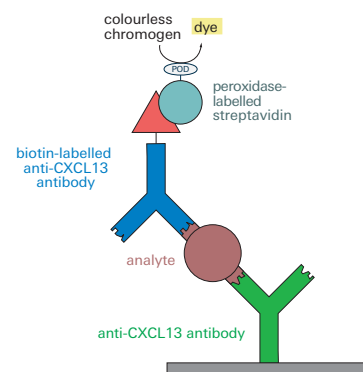
Diagnostic application

The EUROIMMUN ELISA is the first CXCL13-ELISA approved for in vitro diagnostics. The test enables reliable and precise quantification of CXCL13 in CSF. In patients with acute neuroborreliosis, in early stages of the disease, high concentrations of CXCL13 are frequently observed, often even before antibodies against Borrelia are detectable. CXCL13 determination can help close the gap between infection and positive antibody test and to diagnose neuroborreliosis at an earlier stage. CXCL13 is also suitable as a marker for the disease course after treatment. Its concentration in CSF decreases with successful therapy. It needs to be taken into account that increased CXCL13 values can also be observed in other diseases, in particular in neurosyphilis, HIV meningitis, streptococcus infections, toxoplasmosis and multiple sclerosis.



Test principle

In the first reaction step, undiluted patient samples and biotin-labelled anti-CXCL13 antibodies are pipetted into the microplate wells which are coated with monoclonal anti-CXCL13 antibodies. CXCL13 is then bound in a complex. In the second incubation step, this complex is labelled with peroxidase-labelled streptavidin. In the third incubation step, the bound peroxidase and the peroxidase substrate tetramethylbenzidine (TMB) catalyse a colour reaction. The intensity of the colour formed is proportional to the CXCL13 concentration in the sample.



Detection limit

The lower detection limit is defined as the mean value of an analyte-free sample plus three times the standard deviation and is the smallest clearly detectable CXCL13 concentration. The average lower detection limit of the CXCL13 ELISA is 4.6 pg/ml. The functional sensitivity, defined as the lowest concentration of a sample with a variation coefficient <20% was determined as 10.7 pg/ml.

Reproducibility

The reproducibility of the test was investigated by determining the intra-assay, inter-assay and inter-lot coefficients of variation (CV) using 3 samples.

No.	Intra-assay precision, n = 20		No.	Inter-assay precision, n = 10x3		No.	Inter-lot precision, n = 3x3x2	
	Mean value (pg/ml)	CV (%)		Mean value (pg/ml)	CV (%)		Mean value (pg/ml)	CV (%)
1	27	7.7	4	21	11.6	7	18	9.9
2	48	4.3	5	181	6.3	8	63	5.7
3	233	6.4	6	340	8.0	9	358	6.7

Expected values

I: 279 CSF samples from patients with unknown anamnesis (no known cases of neuroborreliosis) were investigated with the EUROIMMUN CXCL13 ELISA. 90% of CSF samples showed a CXCL13 level <20 pg/ml.

II: Clinically characterised CSF samples from 12 neuroborreliosis patients were investigated with the EUROIMMUN CXCL13 ELISA. The CXCL13 levels in CSF in all samples were >100 pg/ml, in 9 cases >500 pg/ml.

Correlation of the EUROIMMUN CXCL13 ELISA with R & D Quantikine ELISA

The CXCL13 concentrations of 57 CSF samples were determined with the EUROIMMUN CXCL13 ELISA and the R & D Quantikine ELISA. The linear regression analysis yielded a regression coefficient of $R^2 = 0.97$.

