

Survey for *Borrelia burgdorferi* IgM-Antibody Index (BOR-M-AI)

EQA Provider: ESfEQA GmbH
Heidelberg

Survey Coordinator: Dr. H. Depner

Instructions for Use

Notes:

The samples should be considered as potentially infectious. The usual precautions in the laboratory for potential hazardous samples apply for these samples. The blood donations used for production were found to be non-reactive for HBsAg, anti-HIV 1/2 and anti-HCV. The samples should be used by trained personnel only



WARNING: Contains methylisothiazolones. H317 May cause allergic skin reaction.



This product contains human source material and should be considered as potentially infectious.

Various tasks of the proficiency testing scheme may occasionally be given over to qualified subcontractors. However, ESfEQA is responsible to the participants for the subcontractor's work.

Results from sample analysis may only be disclosed to colleagues from other laboratories after the testing period has been concluded.

By registering for and participating in this EQA participants agree to accept the general terms and conditions of ESfEQA GmbH. These can be retrieved online at www.esfeqa.eu

1. Intended Use

The samples are intended for use as qualitative and quantitative control material for External Quality Assessment (EQA) in medical laboratories for following parameters:

Borrelia-IgM-Antibody Index (AI) (quantitative)

Borrelia-IgM-Antibody Index (AI) (qualitative)

The calculation of the AI using the selected reference value of Q_{IgX} or $Q_{Lim\ IgX}$ is performed according to the procedure of Prof. Dr. Hansotto Reiber^{1,2}.

2. Product Description

Sample 1: BOR-M-AI_2025_02_a (Liquor/CSF)

Sample 2: BOR-M-AI_2025_02_b (Serum)

The samples are liquid and ready-to-use. The CSF sample consists of native pooled CSF to which a defined amount of antibody-positive serum has been added in accordance with the objectives of the EQA survey. The serum sample is derived from defibrinated human plasma.

3. Storage and Stability

The samples should be stored upright at 2-8 °C. They are stable at least until the deadline for data submission as indicated below.

4. Sample Preparation and Analysis

Allow the sample to equilibrate to room temperature for 15 minutes prior to testing. Directly before use, agitate the sample by gently inverting the vial several times.

All samples should be treated the same way as patient samples and analyzed in accordance with the instructions of the instrument and reagent manufacturer.

Depending on the antibody concentration in the samples, dilutions or combinations of dilutions of the CSF and serum samples may be necessary that are different from the specifications (initial dilutions) of the reagent manufacturer. **In particular, higher dilutions of the CSF sample may be necessary in case of intrathecal synthesis of *Borrelia* IgM antibodies.**

If a sample yields a result above the measuring range, it should be analyzed at a higher dilution. Additional dilution factors should be included for the obtained antibody values with regard to the calculation of the AI quotient.

5. Clinical information for the calculation of the Antibody Index

Age of the patient: **65 years old**

Laboratory results:

Albumin (CSF)	657 mg/L
Albumin (Serum)	43.8 g/L

Total IgM (CSF)	6.1 mg/L
Total IgM (Serum)	1.9 g/L

6. Dates and Submission of Test Results

Testing Period for Sample 1 and 2: 28/10/25 - 18/11/25

Please submit your results electronically to ESfEQA at <https://teqa.esfeqa.eu>.

Contact your local distributor of ESfEQA programs or ESfEQA directly if you need assistance with registration in TEQA. Alternatively, though not preferred, use the fax form provided on the ESfEQA website. In both cases indicate the instrument and method used for the analysis of the samples.

7. Deadline for Result Submission

Deadline for data submission (time zone GMT +1):

18/11/25

8. Reports and Certificates

The data will be evaluated by ESfEQA.

The individual laboratory reports and certificates can be retrieved online at <https://teqa.esfeqa.eu>.

9. References

1. Reiber H (1994). Flow rate of cerebrospinal fluid (CSF) – a concept common to normal blood-CSF barrier function and to dysfunction in neurological diseases. *J Neurol Sci* 122: 189–203.
2. Reiber H, Peter JB (2001). Cerebrospinal fluid analysis: disease-related data patterns and evaluation programs. *J. Neurol. Sci.* 184, 101 – 22.