VIROTECH Antibody index control

Control for determination of antibody index in CSF diagnosis

Borrelia + VlsE IgG Liquor/CSF AI Ctrl-Set
Order No.: EN022L65

FOR IN VITRO DIAGNOSIS ONLY

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Freigabedatum: 18.09.2024 10:17
REV 19 / VIROTECH Liquor/CSF AI Ctrl-Set EN

Content

1. Introduction

Determination of the antibody index allows identification of synthesis of organism-specific antibodies in the central nervous system. It is is calculated from the quotient of the ratios of the organism-specific antibodies in cerebrospinal fluid and serum and the total immunoglobulin ratio from cerebrospinal fluid and serum.

2. Purpose

The antibody index paired controls are used in infection serology diagnosis in the cerebrospinal fluid for determining the accuracy and precision of the antbody index and allow comprehensive quality control in daily routine laboratory cerebrospinal fluid diagnosis.

The target values of the cerebrospinal fluid/ serum paired controls are chosen to allow control of antibody indices in the normal range (AI < 1.4) and abnormally high antibody indices (AI > 1.5).

3. Package contents

1. **Cerebrospinal fluid/serum paired controls for the normal range (AI<1.4)**
   Cerebrospinal fluid, 1 ml, (Cerebrospinal fluid matrix equivalent material from highly diluted human serum with addition of protein stabilisers and preservatives, ready to use)
   Serum, 1 ml, human serum with protein stabilisers and preservatives, ready to use.
2. **Cerebrospinal fluid/ serum paired controls for the abnormal range (AI>1.5)**
   Cerebrospinal fluid, 1 ml, (Cerebrospinal fluid matrix equivalent material from highly diluted human serum with addition of protein stabilisers and preservatives, ready to use)
   Serum, 1 ml, human serum with protein stabilisers and preservatives, ready to use.

4. Storage and shelf life of ready to use reagents

The shelf life of individual components is marked on the label; kit shelf life see quality control certificate.

Material	Status	Storage	Shelflife
Controls	After Opening	+2 to +8°C	3 months

5. Precautions

1. For control serum, only serum that has been tested and found to be negative for HIV1 Ab, HIV2 Ab, HCV Ab and Hepatitis B surface antigen is used. However, controls, conjugated and microtitre strips should be regarded as potentially infectious material and handled with appropriate care. The current guidelines for laboratories should be observed.
2. The disposal of used materials must comply with the State-specific guidelines.

6. Test performance

Exact performance according to the instructions for use is a prerequisite for achieving correct results.

6.1 VIROTECH ELISA test performance

1. Pipette 100 µl of ready to use AI controls per test run in a batch in parallel with the standard sera and patient sera or cerebrospinal fluid.
2. After pipetting, incubate for 30 minutes at 37 °C.
3. End the incubation period by washing 4 times with 350-400µl wash solution per well.
4. Pipette 100µl of ready to use conjugate into each well.
5. Incubation of conjugate: 30 minutes at 37°C .
6. End the conjugate incubation by washing 4 times (see Paragraph 3).
7. Pipette 100µl of ready to use TMB substrate solution into each well.
8. Incubation of substrate solution: 30 minutes at 37°C (dark incubation).
9. Stop the substrate reaction: pipette 50 µL citrate stop solution into each well.
10. Measure extinction at 450/620nm. The photometric measurement should be carried out within one hour of adding the stop solution.

Test performance diagram – see last page

7. Test evaluation

By determining the arbitrary measurement units (according to the instructions in the VIROTECH cerebrospinal fluid standard kit) and taking into account the dilutions (Serum 1:400 and cerebrospinal fluid 1:2), the organism specific IgX ratio can be calculated. By forming the ratio of the organism specific raio and the total IgX ratios given in the certificate (batch specifi), the antidboy index can be calculated.

On request, Gold Standard Diagnostics Frankfurt GmbH provides customers with an MS Excel evaluation program. This automatically calculates and evaluates the antibody index (order number: EX-CSF-GB).

7.1 Interpretation of results

The AI values given in the supplied certificate and the confidence intervals are valid for the batch. The AI values determined in the test run can be regarded as valid if the values for the AI controls lie within the given confidence limits. Each laboratory should undertake appropriate correction measures if the determined AI values lie outside the confidence limits.

The AI controls were confirmed by performing tests in a reference laboratory to confirm the AI range.

Preparation of Washing Solution

▼ **Washing Solution:** Fill up concentrate to 1 liter with aqua dest./demin.

Testprocedure

Samples Incubation	**30 minutes at 37°C**	**100 µl Antibody index Control**
⇩		
Wash 4times		**400 µl Washing Solution** Remove Residues on a Cellulose Pad
⇩		
Conjugate Incubation	**30 minutes at 37°C**	**100 µl Conjugate** IgG
⇩		
Wash 4times		**400 µl Washing Solution** Remove Residues on a Cellulose Pad
⇩		
Substrate Incubation	**30 minutes at 37°C**	**100 µl Substrate**
⇩		
Stopping		**50 µl Stopping Solution** shake carefully
⇩		
Measure Extinctions		**Photometer at 450/620nm**