IDEIA Lyme Neuroborreliosis

1. INTENDED USE

The IDEIA Lyme Neuroborreliosis test is an enzyme immunoassay for the detection of intrathecally produced IgG and IgM antibodies to Borrelia burgdorferi sensu lato. The test is intended as an aid in the diagnosis of Lyme neuroborreliosis.

2. SUMMARY

Involvement of the nervous system, neuroborreliosis, is a common and serious manifestation of Lyme borreliosis. Involvement of the nervous system, neuroborreliosis, is a common and serious manifestation of Lyme borreliosis.

A sensitive and reliable diagnostic test for neuroborreliosis is needed as a number of other diseases with similar symptoms can be present in neuroborreliosis, in contrast to many of these diseases, responds to antibiotic treatment.

Currently, the best indicator of active neuroborreliosis is an intrathecal antibody response (1-4). In contrast to many of these diseases, neuroborreliosis, in contrast to many of these diseases, responds to antibiotic treatment. Furthermore, the use of flagellin as test antigen is advantageous compared with other Borrelia antigens.

The IDEIA Lyme Neuroborreliosis kit is for the testing of paired CSF and serum specimens. Results are given as optical density (OD) values, which are compared with OD values obtained with positive and negative controls. The OD value of the patient’s sample is compared with the OD values of the positive controls, provided with the kit. The OD value of the patient’s sample is compared with the OD values of the positive controls, provided with the kit.

The test is based on the ELISA principle and consists of a human IgG capture assay and a human IgM capture assay for determination of intrathecally produced IgG and IgM antibodies to B. burgdorferi, respectively. The human IgM capture assay is described in Section 5.2.

3. DESCRIPTION OF THE TEST

The concentrations of Borrelia burgdorferi-specific IgG and IgM antibodies in the CSF can be measured using the IDEIA Lyme Neuroborreliosis kit. The test is intended for the detection of intrathecally produced IgG and IgM antibodies to Borrelia burgdorferi sensu lato. The test is intended as an aid in the diagnosis of Lyme neuroborreliosis.

4. TECHNICAL SPECIFICATIONS

The IDEIA Lyme Neuroborreliosis kit consists of one reagent kit for the test antigen and one negative control kit. The test antigen is the outer flagellum of B. burgdorferi sensu lato. The test antigen is the outer flagellum of B. burgdorferi sensu lato. The test antigen is the outer flagellum of B. burgdorferi sensu lato.

5.2.5 IgM Positive Control

100 mL Diluent: Buffered solution with detergent, anti-microbial agent and coloured red dye.
50 mL Wash Buffer concentrate: Buffered solution with detergent and anti-microbial agent.
50 mL Substrate: Stabilized peroxide and buffer with antimicrobial agent and coloured green dye.
12 mL ReconstitutedBuffer solution with anti-microbial agent and coloured blue.
1 mL Peroxide Complex: Peroxide-complex NParaffin microwell carrier protein and anti-microbial agent.
12 mL Substrate: Stabilized peroxide and 3,3’-5,5’-tetramethylbenzidine in a dilute buffer. The formation of a blue product is non-carcinogenic. However, personal protective equipment is recommended to avoid direct exposure.
25 mL Stop Solution: 0.4M NaOH.

5. PREPARATION, STORAGE AND RE-USE OF KIT COMPONENTS

The IDEIA Lyme Neuroborreliosis kit format allows for up to 6 tests. Each patient specimen is used by the same microtiter plate. Each patient specimen is used by the same microtiter plate. Each patient specimen is used by the same microtiter plate.

5.2.1 Microtitre plates - Borrelia burgdorferi specific

The test is based on the ELISA principle and consists of a human IgG capture assay and a human IgM capture assay for determination of intrathecally produced IgG and IgM antibodies to B. burgdorferi. Borrelia burgdorferi-specific IgG only, whereas non-B. burgdorferi-specific IgG will not bind the Flagellum Conjugate.

Excess Flagellum Conjugate is removed by washing. The amount of Flagellum Conjugate bound per microwell is visualized by the formation of a blue product. The kit contains enough Flagellum Conjugate for 100 tests.

5.2.2 Wash Buffer Concentrate

Preparation of the Wash Buffer is required before use. Add 1 part of Wash Buffer Concentrate to 2 parts distilled or deionized water (or add the contents of Wash Buffer Concentrate to 100 mL distilled or deionized water). Mix gently.

5.2.3 Substrate Addition and Incubation

The microwells should be washed using working strength Wash Buffer provided with the kit. The microwells should be washed using working strength Wash Buffer provided with the kit. The microwells should be washed using working strength Wash Buffer provided with the kit.

5.3.2 Reconstitute Flagellum Conjugate by incubation with Wash Buffer Concentrate.

Reconstituted Flagellum Conjugate is to be stored at 2-8°C and used within 3 months.

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6. TEST PROCEDURE

The reconstituted Flagellum Conjugate must be prepared at least 1 hour prior to use. The reconstituted Flagellum Conjugate should be stored at 2-8°C and used within 3 months.

Use 14.6 mL of Wash Buffer concentrate to each microwell of Flagellum Conjugate.

5.4.4 Substrate Addition and Incubation

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6.5.5 IgM Positive Control

Ready to use. Store unused IgM Positive Control at 2-8°C.

6.5.6 IgM Positive Control

Ready to use. Store unused IgM Positive Control at 2-8°C.

6.5.7 IgM Positive Control

Ready to use. Store unused IgM Positive Control at 2-8°C.

6.5.8 IgM Positive Control

Ready to use. Store unused IgM Positive Control at 2-8°C.

6.5.9 IgM Positive Control

Ready to use. Store unused IgM Positive Control at 2-8°C.
10.4. SUMMARY OF IDEA LYMNEUROBORRELIOSIS ASSAY PROCEDURE

11. QUALITY CONTROL AND INTERPRETATION OF RESULTS

11.1. BUFFER CONTROL
Calculate the mean OD values of the 2 Buffer Control microwells. The mean OD value of the Buffer Control must be less than 0.010, but greater than 0.000 (dual wavelength reading). If the value is less than 0.000, the user or the reader should be alerted that the medium is re-added.

The quality control requirements are not satisfied, test results are invalid and the assay should be repeated.

11.2. IgG POSITIVE CONTROL AND IgM POSITIVE CONTROL
Calculate the mean OD values for IgG Positive Control and IgM Positive Control. Individual OD values of duplicate test should not differ more than 15% from the mean. Any such tests should be retested. However, if the test results should show a result negative a difference of more than 15%, they should be accepted without retesting because low OD values are measured with less precision.

The specific antibody index formula is given below. Calculate the specific antibody index for IgG (IgG) and IgM (IgM), respectively. The index calculation should not be performed if the mean OD value of the CSF determination is less than 0.150. Any such test result should be reported as negative.

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I = \frac{OD_{CSF} - OD_{serum}}{OD_{serum} \times (OD_{CSF} - OD_{serum})}
\]

11.4. INTERPRETATION OF RESULTS

11.4.1. Qualitative Interpretation
Interpret as follows:

- Negative for production of intrathecal IgG antibodies to B. burgdorferi:
  - I = 0.3

- Positive for production of intrathecal IgG antibodies to B. burgdorferi:
  - I > 0.3

- Negative for production of intrathecal IgM antibodies to B. burgdorferi:
  - I < 0.3

- Positive for production of intrathecal IgM antibodies to B. burgdorferi:
  - I > 0.3

11.4.2. Semiquantitative Interpretation
The higher the obtained index, the more pronounced is the specific intrathecal antibody production. Indices values may be 100 or more.

A specific antibody index I ≥ 0.5 always indicates intrathecal synthesis of specific antibodies.

In patients with neuroborreliosis, intrathecal antibody synthesis usually begins in the second week after onset of neurological symptoms. Specific IgG and/or IgG production is detectable in 80% of patients with definite neuroborreliosis by the beginning of the third week and in all patients 6-8 weeks after onset of neurological symptoms.

Absence of intrathecal antibody production or the presence of specific antibodies in CSF due to transudation or blood contamination of CSF will give antibody indices ≤ 0.3.

12. SPECIFIC PERFORMANCE CHARACTERISTICS

Paried CSF and serum specimens from 25 patients with clinically defined early Lyme neuroborreliosis were tested with the IDEA Lyme Neuroborreliosis assay.

12.1. EXPERIMENTAL LIMITATIONS

- A specific antibody index I ≥ 0.5 always indicates intrathecal synthesis of specific antibodies.

13. EXPECTED VALUES

A specific antibody index I ≥ 0.5 always indicates intrathecal synthesis of specific antibodies.

15. REFERENCES

- Hansen K, Cruz M, Link H. (1990)
- Steen AE, Godal RA, Barbour AG, et al. (1986)
- De Serres F, Gispen BH, et al. (1988)
- Craft JE, Duncan KF, Shimamoto GT, Steere AC. (1986)
- IFU X7840B Revised January 2017

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For all enquiries please contact your local distributor.