IBL-America Control Serum

to be used for any ELISA test kit coded IB05xxx

Order No.: IB05xxxCON

Instructions for Use

1. Composition

Pathogen-specific positive material (antibodies in human serum) in protein-containing phosphate buffer with Tween 20.

liquid, 1 x 3 ml; tested negative for anti-HIV Ab, HBs-Ag (Hepatitis B-Virus surface antigen) and anti-HCV Ab; preservative: < 0.1 % sodium azide; colouring: 0.01 g/l Bromphenol blue.

2. Intended Use

These controls are positive control sera for monitoring qualitative antibody determination when using immunoassays from the IBL-America product line coded IB05xxx. They are to be regarded as additional controls to the reagents supplied with the test kits. They are used to determine validity of IBL-America ELISA test runs as well as precision and reliability of the method. IBL-America ELISA controls are particularly recommended as an aid for internal quality management in accredited laboratories. Controls can be processed manually or automatically. The tests are designed for professional use.

3. Stability and Storage

The unopened ready-to-use controls are stable for 24 months from date of production when stored at 2-8 °C; The opened ready-to-use controls are stable for 24 months from date of production when stored at 2-8 °C; expiry date see label. Do not freeze.

4. Target Values and Target Ranges

In comprehensive validation studies, target values and target ranges for each test-specific IBL-America ELISA control are determined and documented on lot-specific certificates of analysis. These are recommended as control values for the quality management in accredited laboratories when using IBL-America ELISA controls with the corresponding IBL-America ELISA kits coded IB05xxx. These ELISA controls generally show positive results in test runs with ELISA kits coded IB05xxx. However, a few tests were evaluated to correspond to a so-called threshold, e.g. in order to exclude high seroprevalences. Therefore, the evaluation of individual ELISA controls might deliver borderline results in exceptional cases.

5. Preparation

These ELISA controls are ready-to-use and must not be diluted any further. Rf-absorption must not be performed. These ELISA controls must be brought to room temperature before using. Before pipetting, the ELISA controls should be agitated (e.g. by using a vortex mixer) in order to ensure a homogenous solution.

6. Performance

In course of the test run pipette 100 µl of these ELISA control into the cavity of the corresponding ELISA test strip. These ELISA controls are recommended to be used in each ELISA test run and the results recorded on a control chart. These ELISA controls are recommended for use with the corresponding ELISA test kit coded IB05xxx. Please also refer to the instruction manual of the ELISA.

7. Restriction

IBL-America ELISA control must not be used after expiry date. Discard the vial if there is evidence of microbial contamination or if the product becomes very cloudy. These ELISA controls are intended for use with the corresponding test coded IB05xxx and are independent of the controls supplied with the IB05xxx ELISAs. They are not suitable for use as standard. These ELISA controls can be used with other tests only after validation by the user.

8. Safety and Precautions

8.1 Statement of Warning

The IBL-America ELISA control is designed for use by professional who are familiar with laboratory techniques. All kit reagents and human specimens should be handled carefully, using established laboratory techniques.

- Although all IBL-America ELISA controls have been found to be negative for HBsAg, HCV and HIV-antibodies, they should be considered potentially infectious. The product contains sodium azide as a preservative. Swallowing and contact with skin or mucous membranes must be avoided!
- Do not pipette by mouth
- Do not smoke, eat or drink in areas in which specimens or kit reagents are handled.
- Wear disposable gloves, laboratory coat and safety glasses while handling kit reagents or specimens. Wash hands thoroughly afterwards.
- Potentially infectious material should be decontaminated after the test run.
- Reagents should be stored safely and be inaccessible to unauthorized access e.g. children.

8.2 Disposal

- Please observe the relevant statutory requirements!

8.3 Serious incidents

Serious incidents that have occurred in connection with the product must be reported to the manufacturer and the competent authority.

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