

IVD

PRODUCT INFORMATION

REF 36214000

Negative Control for Allergozyme[®] Spec. IgE



LOT M08060XX

Intended use

The negative control is only suitable for checking the accuracy of Omega Diagnostics Spec. IgE. The instructions for use of the particular test kit must be observed. It is recommended to determine at least one control allergen per test run. If the value is above the accepted range, the possible cause must be determined before the results are released. If necessary Omega Diagnostics should be contacted.

Content

The vial contains a lyophilised pool serum to be reconstituted. The final volume is 1.0 ml.
0.05 % sodium azide (Preservative).

Control values

The negative control is negative for the allergen discs **t 3** (Birch pollen), **d 1** (Dermatophagoides pteronyssinus) and **g 6** (Timothy grass) (< 0.35 U/ml resp. < EAST class 1).

Reconstitution / preparation of the negative control

Open the vial and add 1.0 ml of distilled water to the lyophilisate. The vial must be resealed with the original stopper and left for 15 min. The lyophilisate is dissolved by gently shaking the vial occasionally. Carefully mix the serum before use. The serum should be treated the same way as patient specimens.

RCNS 1.0 ml H₂O DIST = reconstitute with 1.0 ml distilled water

Storage and stability

Originally sealed the serum is stable until the date printed on the label at 2 to 8°C. Reconstituted serum is stable for up to 5 days at 2 to 8°C. The serum may be portioned for use and stored at –20°C for a maximum of 2 years. Avoid to freeze / thaw serum several times!

Attention: Never intermix stoppers with other vials!
The control values only refer to the lot number indicated.

Warnings and precautions

The serum was tested by FDA approved methods and was found to be non-reactive for hepatitis-B surface antigen (HB_s Ag), antibodies to hepatitis-C (HCV) and antibodies to HIV-1/HIV-2. However, all material of human origin must be considered to be potentially infectious. Therefore, handle the serum with the same precautions as used for patient specimens.

Manufacturer

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