

IVD

PRODUCT INFORMATION

REF 36215001

**Positive Control
for Allergozyme[®] Total IgE**



LOT M1402903 X

Intended use

The positive control is only suitable for checking the accuracy of Omega Diagnostics Allergozyme[®] Total IgE. The instructions for use of the test kit must be observed. The test method is considered to be working correctly if values are generated within the accepted range (see under "Control values"). **Exact achievement of the mean value is not a necessary precondition for meeting the accuracy criteria.** If the value is outside 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 0.5 ml.
0.05 % sodium azide (Preservative).

Control values

Mean Value (IU/ml)	Acceptable Range (IU/ml)
89	47 - 132

Reconstitution / preparation of the positive control

Open the vial and add 0.5 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 0.5 ml | H₂O | DIST = reconstitute with 0.5 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 repeated freezing and thawing of the serum!

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

Omega Diagnostics GmbH
Herrengarten 1
D-21465 Reinbek – Germany
☎ ++49-40-636654-100
Fax++49-40-636654-111