

**IVD**

**PRODUCT INFORMATION**

**REF 36211000**

**Positive Control  
for Allergozyme® Spec. IgE**



**LOT M14117XX**

**Intended use**

The positive 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. 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. It is recommended to determine 1 to 3 control allergens per test run. If one of the values 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 lyophilised pool plasma to be reconstituted. The final volume is 1.0 ml. 0.05 % sodium azide (Preservative).

**Control values**

Code	name	EAST- class	
		mean value	accepted range
d 1	Dermatophagoides pteronyssinus	2,4	1,7 – 3,1
e1	Cat epithelia	2,6	1,9 – 3,3
g 6	Timothy grass	2,3	1,6 – 3,0

**Reconstitution / preparation of the positive 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 positive control before use. The positive control should be treated the same way as patient specimens.

**RCNS | 1.0 ml | H<sub>2</sub>O | DIST** = reconstitute with 1.0 ml distilled water

**Storage and stability**

Originally sealed the positive control is stable until the date printed on the label at 2 to 8°C. Reconstituted positive control is stable for up to 5 days at 2 to 8°C. The positive control may be portioned for use and stored at –20°C for a maximum of 2 years. Avoid repeated freezing and thawing of the plasma!

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

**Warnings and precautions**

The positive control was tested by FDA approved methods and was found to be non-reactive for hepatitis-B surface antigen (HB<sub>s</sub> 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 positive control with the same precautions as used for patient specimens.

**Manufacturer**

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