

IVD

PRODUCT INFORMATION

REF 36061002

Positive Control for ECP



valid from 07.03.2013

Intended purpose

The positive control is only suitable for checking the accuracy of the Omega Diagnostics ECP enzyme immunoassay. The instructions for the use of the test kit must be observed. The determination is considered to be adequately performed, if the values generated are within the acceptable ranges (See Section "Control value"). **Exact achievement of the target value is not a necessary precondition for meeting the accuracy criteria.**

Contents

The vial contains 1.3 ml of positive control serum. It contains 1% goat serum.
Preservation agent : 0.09% sodium azide.

Control value

target value: 25 ng/ml	range: 15 – 35 ng/ml
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The stated values were determined with the Omega Diagnostics ECP enzyme immunoassay.

Preparation of the positive control

The control serum must be diluted in the ratio 1+4 with the diluent, i.e. 50 µl of control serum must be diluted with 200 µl diluent solution.

Storage and shelf life


At 2 to 8 °C the serum can be stored until the printed use-by date.

Warning: Do not mix up the screw caps!

Warnings and precautionary measures

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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