

WieslabTM Complement system

Classical pathway

Product no. COMPL CP310

Intended use

The WieslabTM COMPL CP310 kit is an enzyme immunoassay for the qualitative determination of functional classical complement pathway in human serum. For in vitro diagnostic use only.

Principle of the WieslabTM Complement CP assay

The WieslabTM Complement assay combines principles of the hemolytic assay for complement activation with the use of labeled antibodies specific for neoantigen produced as a result of complement activation. The amount of neoantigen generated is proportional to the functional activity of complement pathways.

In the Complement Screen CP kit, the wells of the microtitre strips are coated with specific activators of the classical pathway. Patient serum is diluted in diluent containing specific blocker to ensure that only the Classical pathway is activated. During the incubation of the diluted patient serum in the wells, complement is activated by the specific coating.

The wells are then washed and C5b-9 is detected with a specific alkaline phosphatase labelled antibody to the neoantigen expressed during MAC formation.

After a further washing step, detection of specific antibodies is obtained by incubation with alkaline phosphatase substrate solution. The amount of complement activation correlates with the colour intensity and is measured in terms of absorbance (optical density (OD)).

Kit components and storage of reagents

- One frame with blue coloured break-apart wells (12x8) sealed in a foil pack with a desiccation sachet. The wells have been coated with human IgM.
- 25 mL Diluent CP (Dil CP), labelled blue.
- 13 mL conjugate containing alkaline phosphatase-labelled antibodies to C5b-9 (blue colour).
- 13 mL Substrate solution ready to use.
- 30 mL wash solution 30x concentrated.

- 0,2 mL negative control (NC) containing human serum. (to be diluted as for a patient serum sample).
- 0,2 mL positive control (PC) containing freeze dried human serum, see "Reconstitution of positive control", below.

All reagents in the kit are ready for use except washing solution and controls. The reagents should be stored at 2-8° C except the positive control.

The positive control should be stored at -20° C.