20 Years CMV Serology by medac

Competence - Quality - Continuity

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CMV serology - what medac offers

Require-ments

Our tests meet all the requirements for reliable routine diagnostic testing:

- simple handling - uniform processing and incubation conditions
- ready-for-use reagents
- break-off microtitre strips (individual cavities)
- suitable for use on open microtitre plate automated systems
- pipetting control system (indication system to avoid pipetting failure)

Advan-tages

The IgM- and IgA tests have all the advantages of a μ/α-capture-test:

- no nonspecific and no false-positive results due to rheumatoid factors (Rf), no additional Rf-absorption required
- no blocking of antibodies by high IgG titres

The IgG-ELISA is a quantitative assay:

- the principle of one-point quantification is employed
- the test is calibrated against an international CMV standard from the Bloodbank Lille, thus guaranteeing a high level of diagnostic reliability

The tests are CE-certificated in accordance with the European Guidelines for compulsory licensing of IVD

Appli-cations

Basic diagnostic testing

Determination of immune status

Detection of primary infections

Clarification of primary/reinfection

Special diagnostic testing

Antenatal diagnostic testing

Congenital diagnostic testing

Transplantation monitoring

Avidity measurement with IgG tests

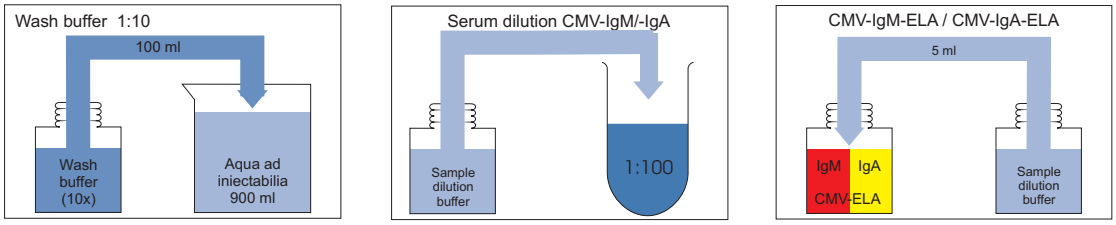
Serum-CSF (cerebrospinal fluid) diagnostics with IgG tests

CMV serology - working diagram

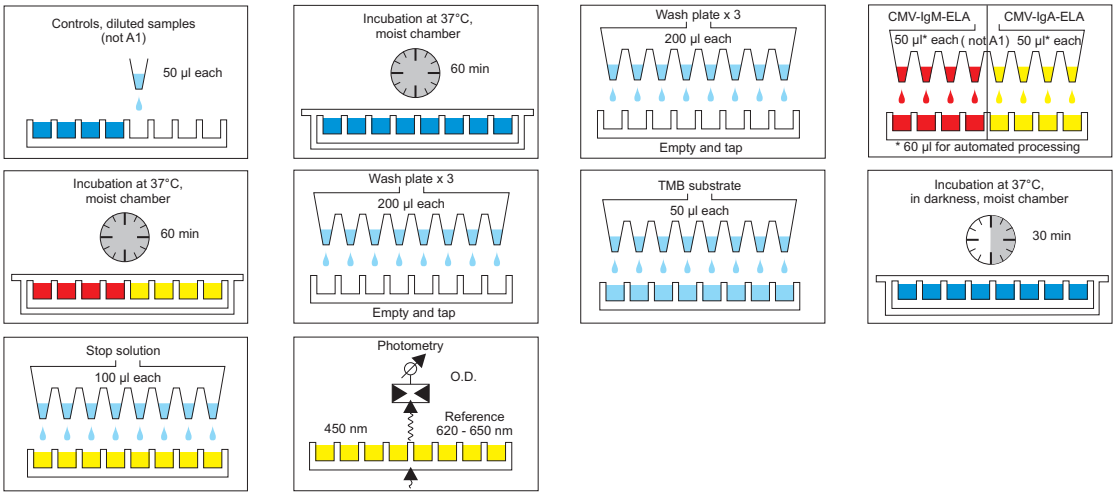
CMV-IgM/-IgA-ELA test PKS

Cat.-No. 110-/112-PKS

Test mixture



Procedure



Evaluation

- The OD mean value of the ***Negative Control must be < 0.100***.
- The OD mean value of the ***Positive Control must be for IgM > 0.800 and for IgA > 0.600***.
- ***Cut-off = OD mean value of the Negative Control + 0.140.***
- ***Limit range = cut off ± 10%.***

Interpretation

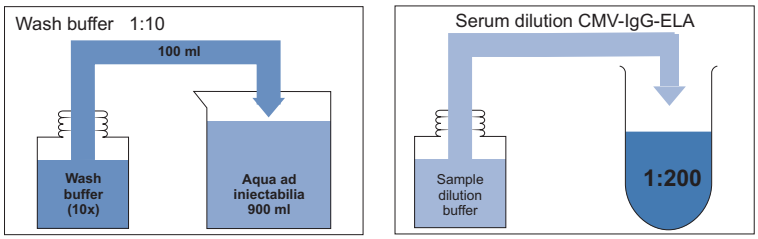
- Samples with OD values below the limit range are assessed as ***NEGATIVE***.
- Samples with OD values within the limit range are assessed as ***BORDERLINE***.
- Results within the limit range should be checked by taking a further specimen from the patient after 14 days. This specimen should be tested together with the original sample to detect any change in titre.
- Samples with OD values above the limit range are assessed as ***POSITIVE***.

CMV serology - brief instruction

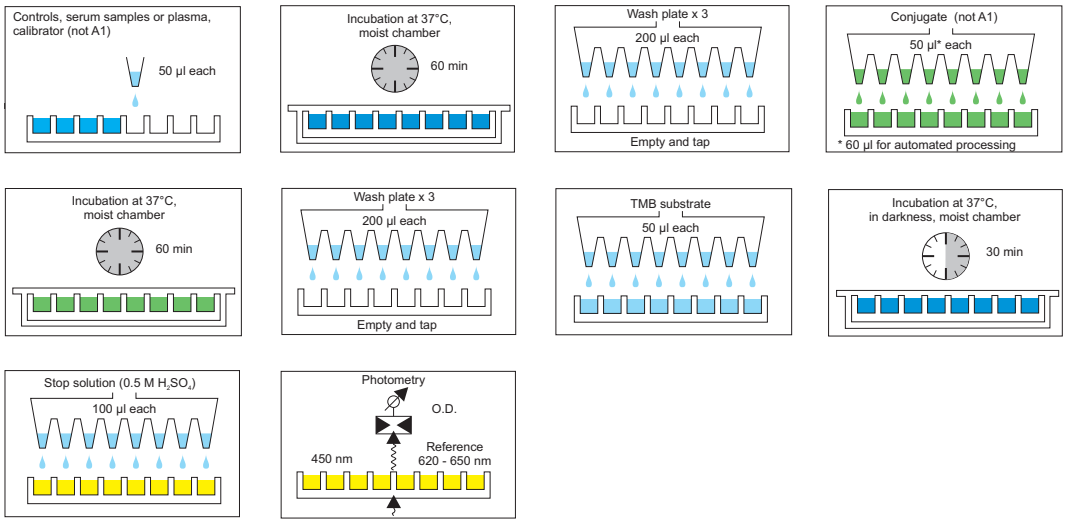
CMV-IgG-ELISA PKS

Cat.-No. 115-Q-PKS

Test mixture



Pro-cedure



Evalu-ation

➤ ***Correction of test results:***

$$OD_{corrected} = \frac{\text{nominal OD value of Calibrator}}{\text{measured OD value of Calibrator}} \times \text{OD as measured}$$

➤ ***Quantification of test results:*** (taking into account batch-specific data):

$$\text{Concentration}\left[\text{AU/ml}\right] = b/\left(\frac{a}{OD_{corrected} - c} - 1\right)$$

➤ ***Cut-off = 0.55 AU/ml.***

➤ ***Limit range = 0.45 - 0.65 AU/ml.***

Inter-pretation

➤ Samples with OD values below the limit range are assessed as ***NEGATIVE***.

➤ Samples with OD values within the limit range are assessed as ***BORDERLINE***.

➤ Results within the limit range should be checked by taking a further specimen from the patient after 14 days. This specimen should be tested together with the original sample to detect any change in titre.

➤ Samples with OD values above the limit range are assessed as ***POSITIVE***.

Date of issue: 05/2004