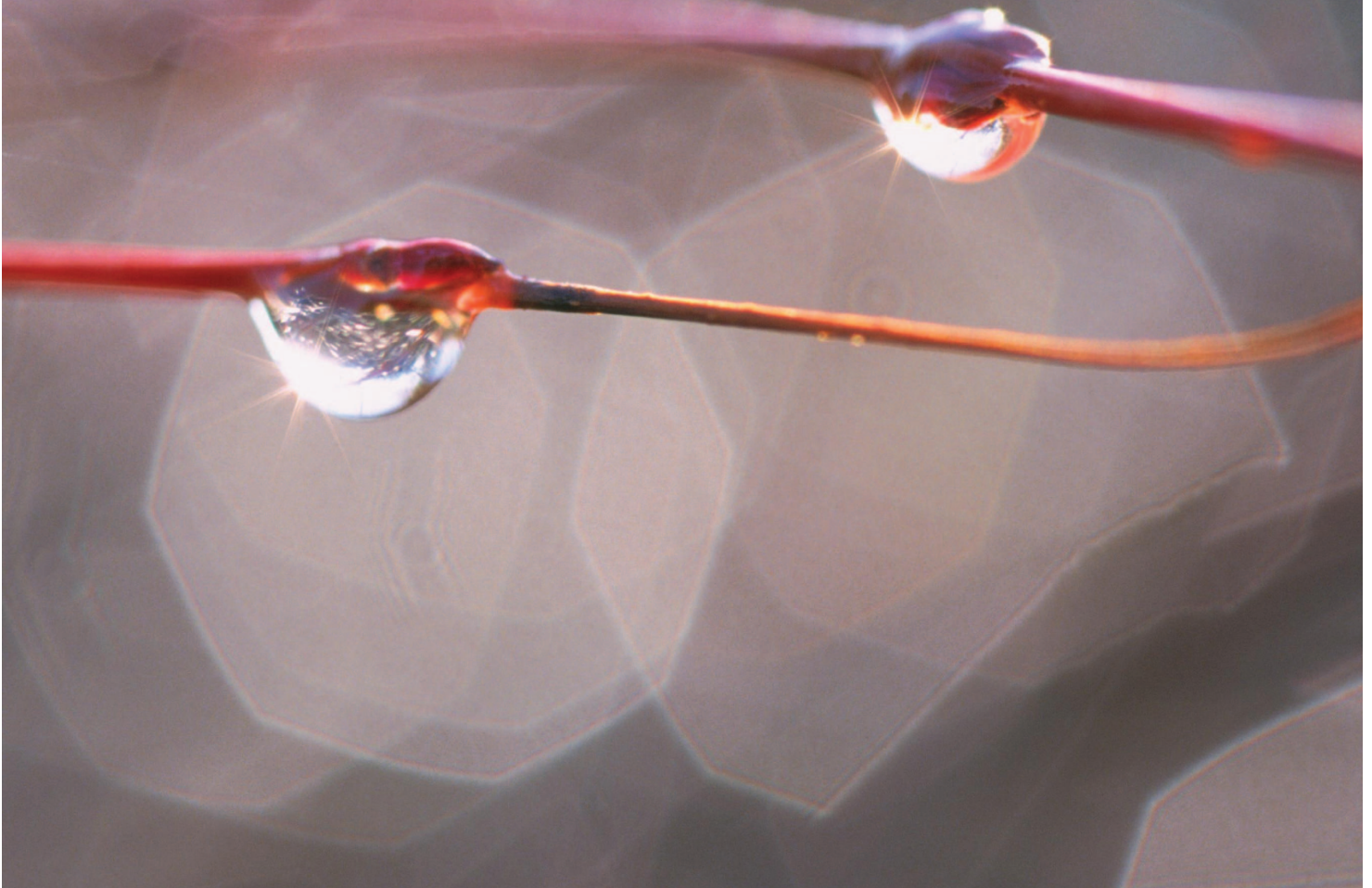


Cytomegalovirus



20 Years CMV Serology by medac

Competence - Quality - Continuity

medac

CMV serology - what medac offers

Requirements

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)

Advantages

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

Applications

Basic diagnostic testing

Determination of immune status
 Detection of primary infections
 Clarification of primary/reinfection

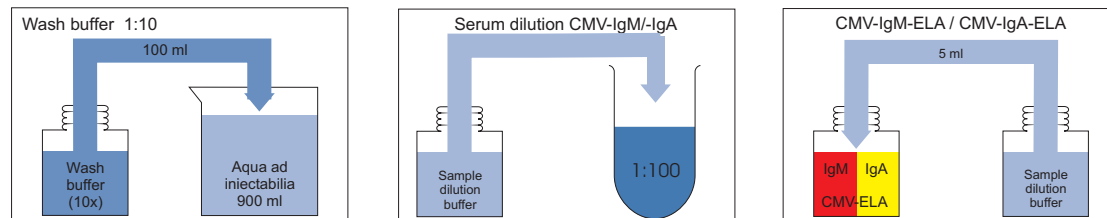
Special diagnostic testing

Antenatal diagnostic testing
 Congenital diagnostic testing
 Transplantation monitoring
 Avidity measurement with IgG tests
 Serum-CSF (cerebrospinal fluid) diagnostics with IgG tests

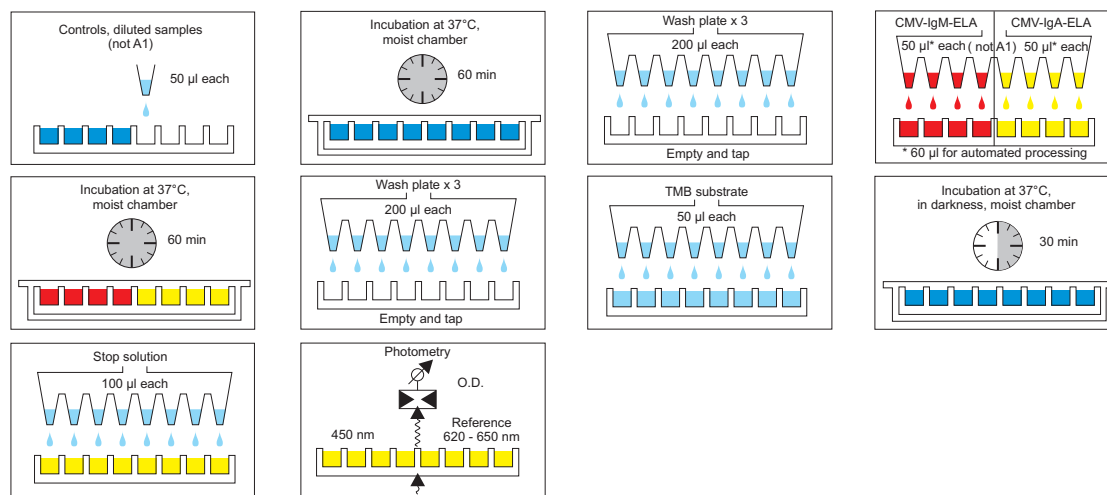
CMV serology - working diagram

CMV-IgM/-IgA-ELA test PKS

Cat.-No. 110-/112-PKS



Test mixture



Pro-
cedure

- 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%**.

Evalu-
ation

- 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**.

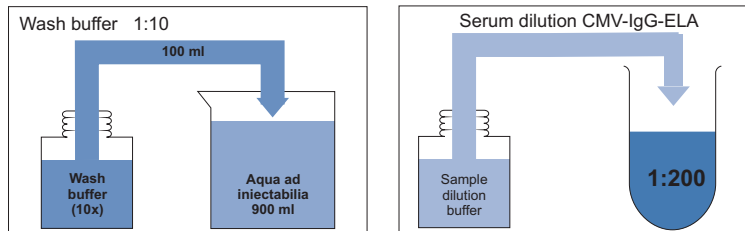
Inter-
pretation

CMV serology - brief instruction

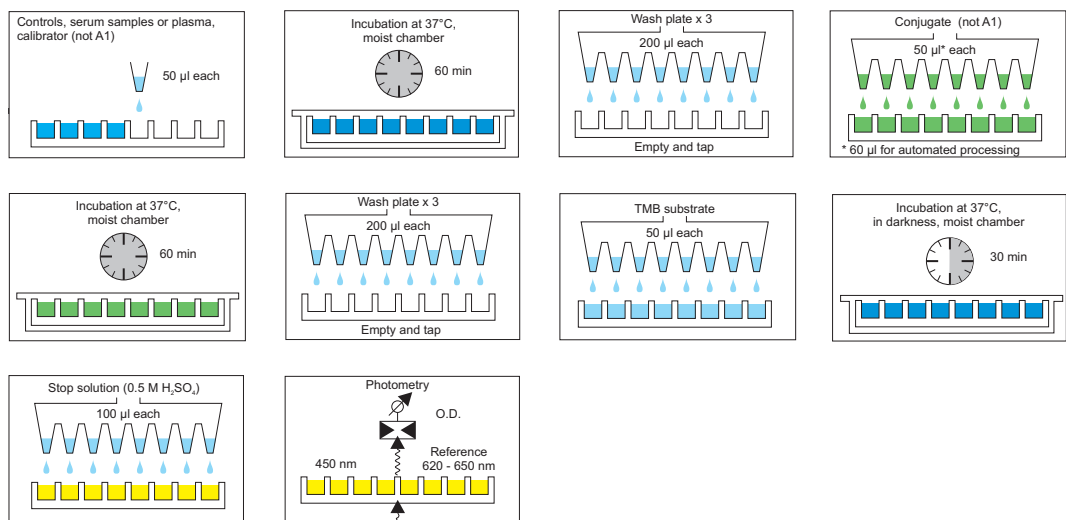
CMV-IgG-ELISA PKS

Cat.-No. 115-Q-PKS

Test mixture



Pro- cedure



Evalu- ation

➤ Correction of test results:

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

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

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

➤ 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.
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