Cytomegalovirus

20 Years CMV Serology by medac

Competence - Quality - Continuity
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

**Test mixture**

- Wash buffer: 1:10
  - 100 µl each
- Serum dilution CMV-IgM-IgA
  - 1:100
- CMV-IgM-ELA / CMV-IgA-ELA
  - 5 ml

**Procedure**

- Controls, diluted samples (not A1)
  - 50 µl each
- Incubation at 37°C, moist chamber
  - 60 min
- Wash plate x 3
  - 200 µl each
- Stop solution
  - 100 µl each
- Photometry
  - O.D.
  - Reference 620 - 650 nm

**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%.**

- 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

- **Wash buffer**: 1:10
- **Aqua ad inyectabilia**: 900 ml

#### Procedure

1. **Controls, serum samples or plasma, calibrator (not A1)**
   - 50 µl each
   - Incubation at 37°C, moist chamber
   - 60 min

2. **Wash plate x 3**
   - Empty and tap

3. **Stop solution (0.5 M H SO₄)**
   - 100 µl each
   - Incubation at 37°C, moist chamber
   - 50 µl each
   - Incubation at 37°C, in darkness, moist chamber
   - 60 min
   - 30 min

4. **Conjugate (not A1)**
   - 50 µl each
   - 10 µl for automated processing

5. **TMB substrate**
   - 200 µl each
   - Wash plate x 3
   - Empty and tap

6. **Proprietary**
   - OD
   - 450 nm
   - Reference: 430 - 650 nm

#### Evaluation

- **Correction of test results**: 
  \[ \text{OD}_{\text{corrected}} = \frac{\text{nominal OD value of Calibrator}}{\text{measured OD value of Calibrator}} \times \text{OD as measured} \]

- **Quantification of test results**: (taking into account batch-specific data):
  \[ \text{Concentration} \left[ \text{AU/ml} \right] = b / \left( \frac{a}{\text{OD}_{\text{corrected}} - c} - 1 \right) \]

- **Cut-off = 0.55 AU/ml.**
- **Limit range = 0.45 - 0.65 AU/ml.**

#### 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**.

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