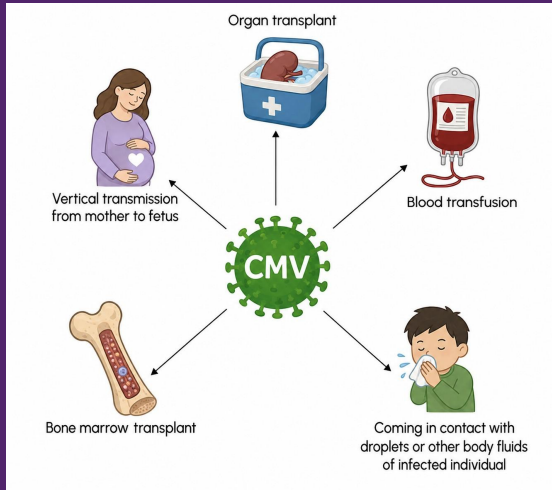




Anti-CMV
IgG/IgM/IgG avidity/IgA
ELISA/MONOTEST

CYTOMEGALO- VIRUS (CMV)

Human Herpesvirus 5 (HHV-5)



Most common congenital viral infection

0.5–2% of all newborns affected globally



Transmission

Occurs through urine, saliva, tears, semen, and breast milk. Stays for life.



In Solid Organ Transplant Patients

May cause: fever-like illness, organ damage, higher risk of other infections and transplant rejection. Also affects immune system activation in immunosuppressed patients.

Cytomegalovirus (CMV) infection during pregnancy is a global silent problem. It is the most common cause of congenital viral infections.

30–40%

risk of vertical transmission from maternal infection to fetus

0.5–2%

incidence of live births affected (most occur in women with prior immunity)

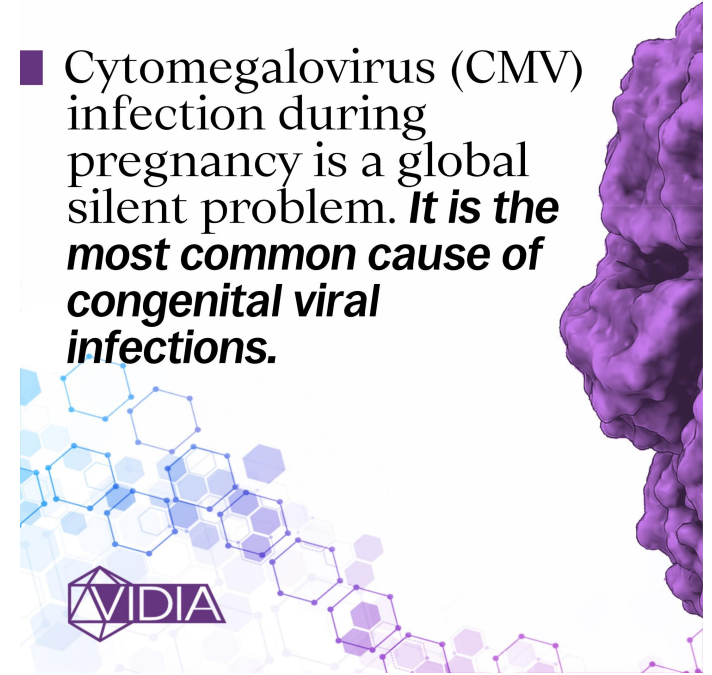
Leading infectious cause of:

Sensorineural hearing loss

Neurodevelopmental impairment

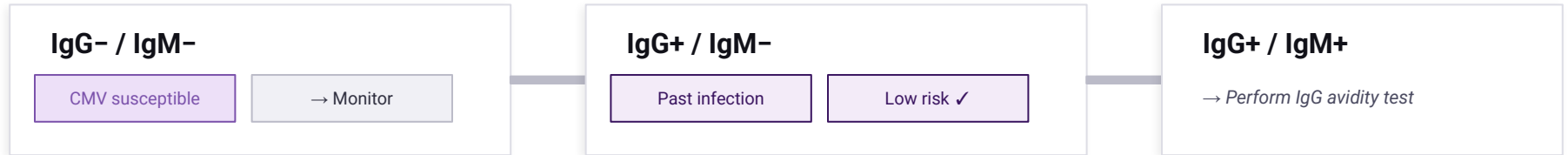
CMV serological testing is essential for risk stratification, prophylaxis, and monitoring

■ Cytomegalovirus (CMV) infection during pregnancy is a global silent problem. ***It is the most common cause of congenital viral infections.***



Laboratory diagnosis of CMV during pregnancy relies on serological assays detecting CMV-specific antibodies (IgG, IgM, and IgG avidity).

Pregnancy Screening Algorithm



Low IgG Avidity

Recent primary infection
(≈ last 2–4 months)

HIGH FETAL RISK

High IgG Avidity

Infection occurred in the past
(safe for pregnancy)

REASSURING ✓

CMV Antibody Panel – When, Why & How to Interpret

CMV IgG

WHEN PERFORMED

- Baseline screening
- Pregnancy (early prenatal visit)
- Organ transplant donors/recipients
- Immunocompromised patients
- Retrospective diagnosis (paired sera)

WHY

Detects past exposure / immunity.
Determines serostatus (IgG+ vs IgG-)

INTERPRETATION

IgG- No prior infection → patient is susceptible

IgG+ Past infection (latent virus persists for life)

► Key role: risk stratification

In pregnancy: IgG- women are at highest risk of primary infection. In transplantation: mismatch (donor+/recipient-) = high risk

CMV IgM

WHEN PERFORMED

- Suspected acute or recent infection
- Abnormal fetal ultrasound findings
- Mononucleosis-like illness with negative EBV tests
- Follow-up of seroconversion

WHY

Indicates recent immune response

INTERPRETATION

IgM+ alone ≠ acute primary infection

► Always requires confirmation with IgG avidity

CMV IgG Avidity

WHEN PERFORMED

- ONLY when IgG+ and IgM+
- Especially critical in Pregnancy
- Suspected recent infection with unclear timing

WHY

Distinguishes primary recent infection vs past infection

INTERPRETATION

Low avidity Recent primary infection (≈ last 2–4 months)

High avidity Infection occurred in the past (safe for pregnancy)

► Key role: timing the infection

Crucial in pregnancy – fetal risk is highest in primary infection

CMV IgA

WHEN PERFORMED

- Less commonly used
- Suspected congenital infection
- Early infection where IgM is unclear
- Specialized labs / research settings

WHY

May indicate active viral replication. Appears early, sometimes alongside or before IgM

INTERPRETATION

Limitations Rarely used alone in routine diagnostics

► Clinical value: supportive marker, not first-line

CMV Diagnostics – Clinical Scenarios

Human cytomegalovirus (CMV): a silent, ubiquitous driver of disease across populations

Human cytomegalovirus (CMV): a silent, ubiquitous driver of disease across populations

Human cytomegalovirus (HCMV), the largest DNA virus in the Herpesviridae family, infects ~80% of the global population—and once acquired, it persists for life.

Why CMV matters

- Establishes lifelong latency with potential for reactivation
- Transmission occurs year-round (no seasonality)
- Particularly relevant in pregnancy, transplantation, and immunosuppression

Pregnancy & congenital infection

- Primary maternal infection → 30–40% risk of vertical transmission
- Most congenital infections occur in women with prior immunity (non-primary infection)
- Leading infectious cause of:
 - Sensorineural hearing loss
 - Neurodevelopmental impairment
- **Incidence: 0.5-2% of live births**

Key risk factor

Close contact with young children (saliva, urine)
→ up to 10x higher risk of infection in women of reproductive age

CMV serology: interpret as a panel—not isolated tests. Each marker answers a different clinical question:

- 1) **IgG** → “Has the patient ever been infected?”
 - IgG → susceptible - IgG+ → past infection (lifelong latency) - **Key role: risk stratification (pregnancy, transplant)**

- 2) **IgM** → “Is there recent immune activity?”

- Indicates possible recent infection. **But:**
- Can persist for months - Seen in reactivation/reinfection - False positives occur. **IgM alone ≠ primary infection**

- 3) **IgG avidity** → “When did infection occur?” (critical test)

- Low avidity → recent primary infection
- High avidity → past infection
- Essential in pregnancy decision-making**

- 4) **IgA** → adjunct marker (limited use)

- May reflect early/active replication
- Not standardized → supportive only

Clinical scenarios (simplified)

- IgG- → high risk → monitor
- IgG+ → generally low risk
- IgG+ / IgM+ → check avidity
 - Low = recent infection (high fetal risk)
 - High = past infection (reassuring)

Suspected acute infection

- IgM + seroconversion → recent infection
- Confirm with avidity if timing matters

Immunocompromised patients

- Serology has limited value - **Use PCR (viral load) instead**

Transplant medicine

- Most common viral complication post-transplant (~20% in first year) • Highest risk: Donor+/Recipient- (D+/R-) • **Risk ↑ with:**
 - Lymphodepleting therapy
 - Lung/small bowel transplants
 - Allograft rejection

1

Pregnancy Screening

IgG/IgM screening from first prenatal visit; avidity for risk stratification of primary vs past infection

2

Suspected Acute Infection

IgM screen for recent immune response; confirm with avidity when IgG+ and IgM+ together

3

Immunocompromised Patients

Serostatus monitoring for reactivation risk; serology alongside PCR for clinical decisions

4

Transplant Medicine

Donor/recipient serostatus mismatch (D+/R-) = highest risk; prophylaxis and monitoring protocol



CMV serology from VIDIA

- ◉ CMV serology is interpreted as a panel, not as isolated tests. Each marker (IgG, IgM, IgG avidity, IgA) answers a different clinical question — mainly: Has the patient ever been infected? Is the infection recent? Is it primary or reactivation?
- ◉ VIDIA CMV assays combine strong clinical performance with operational flexibility and attractive economics, making them a compelling alternative to premium high-throughput automated systems.
- ◉ ELISAs and MONOTESTs for CMV serology from VIDIA support complete, reliable, accurate, and clinically meaningful diagnostics across different patient settings.

VIDIA PROVIDES CMV ELISA SOLUTION

IgG



IgG (CSF)



IgM



IgG avidity



IgA



VIDIA PROVIDES CMV MONOTEST SOLUTION

IgG



IgA



IgM



IgG avidity



Quick Selection Guide – When to Choose VIDITEST

Use VIDIA when any of the following apply:



Small to medium lab volume

Routine batch testing or mid-daily sample loads



Flexible automation needs

Manual operation now with option to add ELISA automation later



Cost-sensitive environments

Lower capital and per-test cost vs high-throughput chemiluminescent platforms



Broad sample access

Need Serum, Plasma (and CSF for specific assays) compatibility



High sensitivity requirement

Outstanding analytical performance validated across assays



Low-resource or decentralized labs

Stable storage (+2 to +10 °C) and straightforward logistics



When rapid ultra-fast TAT is not mandatory

Acceptable when ~75 min result time fits clinical workflow

Summary

1

Cytomegalovirus (CMV) infection during pregnancy is a global silent problem. It is the most common cause of congenital viral infections.

2

CMV is the most common congenital viral infection globally (affecting ~0.5–2% of newborns). It is a leading cause of long-term health problems in children, including: hearing loss, cerebral palsy, vision problems, developmental delays.

3

CMV is often silent – but its long-term impact is significant. More awareness and proper clinical diagnostics are key to improving outcomes.

4

CMV serological testing is essential for risk stratification, prophylaxis, and monitoring.

5

Laboratory diagnosis of CMV infection relies on serological assays detecting CMV-specific antibodies (IgG, IgM, and IgG avidity).

6

Outside of pregnancy, CMV serology is still used – but more selectively, and often alongside PCR or other tests.

7

ELISAs and MONOTESTs for CMV serology from VIDIA support reliable, accurate, and clinically meaningful diagnostics across different patient settings.

8

VIDITESTs have outstanding analytical performance: high sensitivity, high specificity (assay-validated).



THE WAY TO THE CORRECT RESULTS...