NEW TEST – Available Now

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Cytomegalovirus Drug Resistance by Next Generation Sequencing, Letermovir

3004509, CMVNGS

Specimen Requirements:	
Patient Preparation:	
Collect:	Lavender (EDTA), pink (K2EDTA), or plasma preparation tube.
Specimen Preparation:	Separate plasma from cells within 24 hours. Transfer 3 mL plasma to an ARUP Standard Transport Tube. (Min: 2.5 mL)
Transport Temperature:	Frozen.
Unacceptable Conditions:	Serum, heparinized specimens.
Remarks:	If available, please submit the following: most recent viral load and test date; information on current or past drug therapy.
Stability:	After separation from cells: Ambient: 8 hours; Refrigerated: 72 hours; Frozen: 1 month
Methodology:	Massively Parallel Sequencing
Performed:	Sunday-Saturday
Reported:	3-9 days
Note:	This test may be unsuccessful if the plasma CMV DNA viral load is less than 2.6 log IU/mL.
CPT Codes:	87910; 87900
New York DOH Approval Status:	Specimens from New York clients will be sent out to a New York DOH approved laboratory, if possible.

Interpretive Data:

This assay assesses resistance to letermovir. Resistance-associated mutations in the *UL56* gene are sequenced using next generation sequencing. Drug resistance is assigned using an ARUP-developed database of published resistance mutations. For a list of resistance mutations refer to https://ltd.aruplab.com/Tests/Pub/3004509.

This test detects populations down to 10% of the total population which may account for resistance interpretation differences between methods. Some insertions or deletions may be difficult to detect using this software.

Result interpretations are as follows:

• Sensitive indicates no evidence of drug resistance compared with a wild-type virus.
• Possible resistance indicates mutations were detected with borderline-level drug resistance or conflicting resistance status reported in the literature.
• Resistant indicates evidence of drug resistance compared with a wild-type virus.
• Not determined indicates incomplete sequence coverage across a given gene or genes.
• Additional mutations include variants that have not been associated with drug resistance.
• Uncalled mutation sites include drug resistance mutation positions with an inadequate number of sequencing reads.
• Inadequate sequence coverage indicates a low number of sequence reads at a given drug resistance site.

This test was developed, and its performance characteristics determined by ARUP Laboratories. It has not been cleared or approved by the U.S. Food and Drug Administration. This test was performed in a CLIA-certified laboratory and is intended for clinical purposes.

Reference Interval:

By report

HOTLINE NOTE: Refer to the Hotline Test Mix for interface build information.