

Client: Example Client ABC123
123 Test Drive
Salt Lake City, UT 84108
UNITED STATES

Physician: Doctor, Example

Patient: Patient, Example

DOB: 3/20/1960
Gender: Male
Patient Identifiers: 01234567890ABCD, 012345
Visit Number (FIN): 01234567890ABCD
Collection Date: 00/00/0000 00:00

Cytomegalovirus Drug Resistance by Next Generation Sequencing, Ganciclovir, Foscarnet, Cidofovir, Maribavir, and Letemovir

ARUP test code 3004615

CMV Drug Resistance by NGS, 5 Drugs

Indeterminate

Cytomegalovirus Drug Resistance by Next Generation Sequencing is Indeterminate.

In most cases, samples below the lower limit of detection of the assay cannot be sequenced. In addition to low viral load, other conditions such as inhibitors and viral genetic variation may cause sequencing failure and an indeterminate result.

CMVResistanceCaller software version: 2.0.0.1

CMV_resistance_mutations_20220321.db

H=High, L=Low, *=Abnormal, C=Critical

Unless otherwise indicated, testing performed at:

ARUP LABORATORIES | 800-522-2787 | aruplab.com
500 Chipeta Way, Salt Lake City, UT 84108-1221
Jonathan R. Genzen, MD, PhD, Laboratory Director

Patient: Patient, Example
ARUP Accession: 23-299-119469
Patient Identifiers: 01234567890ABCD, 012345
Visit Number (FIN): 01234567890ABCD
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4848

**INTERPRETIVE INFORMATION: CMV Drug Resistance by NGS,
5 Drugs**

This assay assesses resistance to ganciclovir, foscarnet, cidofovir, maribavir, and letermovir. Resistance-associated mutations in the UL97, UL54, UL27, and UL56 genes 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/3004615>.

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.

Drugs associated with each gene are as follows:

- UL97: ganciclovir, maribavir
- UL54: ganciclovir, foscarnet, cidofovir
- UL27: maribavir
- UL56: letermovir

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.

VERIFIED/REPORTED DATES

Procedure	Accession	Collected	Received	Verified/Reported
CMV Drug Resistance by NGS, 5 Drugs	23-299-119469	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00

END OF CHART

H=High, L=Low, *=Abnormal, C=Critical

Unless otherwise indicated, testing performed at: