

Cytomegalovirus Training Panel

CMV Panel, 24 samples (0.6-mL fill volume)









REF: 02-491024

For Training Use

Please contact Quidel Corporation Technical Support for technical assistance regarding this procedure.

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Symbols Lexicon/Glossary

| | | | |
|--|---|---|---|
|  | Temperature limit |  | Batch code/lot number |
|  | Consult e-labeling instructions for use |  | Catalog number |
|  | Manufacturer |  | Use by YYYY-MON-DD |
|  | Authorized representative in the European Community |  | CE mark of conformity (Conformité Européen) |

Intended Use:

For Training use.

The *Cytomegalovirus* (CMV) panel is comprised of 24 frozen 0.6-mL liquid aliquots. Nine of these aliquots have been tested and confirmed to contain viable CMV. The CMV aliquots are used at varying infectious titers. The remaining fifteen aliquots have been tested and confirmed as negative. The panel has been designed for use with cell culture. The validation of this panel with non-cell culture systems is the responsibility of the end-user.

Principle:

Three CMV strains have been propagated in cell culture, diluted and frozen at -70° C. The actual titer in each aliquot is unknown, and has not been quantitatively assayed. Inoculation of this panel should be performed as described in the Product Insert or Instructions for Use of the system in which it will be used.

Storage and handling instructions:

It is recommended that the panel be stored at -70°C or lower. Once the panel has been thawed it should not be re-frozen.

Warnings and Precautions:

1. Personnel working with this panel must be properly trained in virus culture and safe handling techniques.¹
2. Manipulations which present potential personnel hazards should be conducted in a Class II hood with gloves worn at all times and in accordance with the guidelines presented in the CDC-NIH Manual.

¹ Biosafety in Microbiological and Biomedical Laboratories (BMBL), 5th edition, 2007, CDC-NIH manual.
<http://www.cdc.gov/od/ohs/biosfty/bmb15/bmb15toc.htm>

Virus Handling and Usage Instructions:

1. The CMV panel should be transferred from the shipping container to a -70°C or lower freezer immediately upon receipt.
2. At the time of use, rapidly thaw the panel aliquots in a 35° to 37°C water bath.
3. Vortex the aliquots for 10-seconds prior to use.
4. Inoculate the panel aliquots without further dilutions. (200-µL is the recommended volume for inoculation)

CMV Training Panel Key

| Panel Member | Expected Result | Panel Member | Expected Result |
|--------------|------------------------|--------------|------------------------|
| 1 | Negative | 13 | Negative |
| 2 | <i>Cytomegalovirus</i> | 14 | <i>Cytomegalovirus</i> |
| 3 | <i>Cytomegalovirus</i> | 15 | Negative |
| 4 | Negative | 16 | Negative |
| 5 | Negative | 17 | <i>Cytomegalovirus</i> |
| 6 | <i>Cytomegalovirus</i> | 18 | Negative |
| 7 | Negative | 19 | <i>Cytomegalovirus</i> |
| 8 | <i>Cytomegalovirus</i> | 20 | Negative |
| 9 | Negative | 21 | Negative |
| 10 | <i>Cytomegalovirus</i> | 22 | Negative |
| 11 | Negative | 23 | <i>Cytomegalovirus</i> |
| 12 | Negative | 24 | Negative |

Warranty Statement

These products are warranted to perform as described in their labeling and the Diagnostic HYBRIDS literature when used in accordance with their instructions. THERE ARE NO WARRANTIES WHICH EXTEND BEYOND THIS EXPRESS WARRANTY AND DIAGNOSTIC HYBRIDS DISCLAIMS ANY IMPLIED WARRANTY OF MERCHANTABILITY OR WARRANTY OF FITNESS FOR PARTICULAR PURPOSE. Diagnostic HYBRIDS sole obligation and purchaser's exclusive remedy for breach of this warranty shall be, at the option of Diagnostic HYBRIDS to repair or replace the products.