SIEMENS

VERSANT MiPLX Solution

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# kPCR PLX Cytomegalovirus (CMV) DNA Assay

## VERSANT kPCR Molecular System

### Assay Description

The kPCR PLX Cytomegalovirus (CMV) DNA assay is an in vitro diagnostic test for the detection and quantification of CMV-specific DNA in human EDTA plasma specimens. The assay is based on real-time PCR technology, utilizing polymerase chain reaction (PCR) for the amplification of specific target sequences and target-specific probes for the detection of the amplified DNA. The kPCR PLX family of assays is configured for use with the VERSANT® kPCR Molecular System and the VERSANT Sample Preparation 1.2 Reagents Kit.

### Clinical Background

- CMV has a worldwide distribution and infects humans of all ages, with no seasonal or epidemic patterns of transmission.
- Primary infection with CMV results in the establishment of a persistent or latent infection.
- Reactivation of the virus can occur in response to different stimuli, particularly immunosuppression.
- The vast majority of CMV infections are asymptomatic or subclinical.
- In immunocompromised hosts, such as transplant recipients and, HIV-infected or cancer patients, a CMV infection or reactivation may become a life-threatening disseminated disease.

### VERSANT kPCR Molecular System with VERSANT MiPLX Software Solution

Advancing flexibility, workflow, customization, and consolidation in the molecular laboratory.

- Comprehensive and flexible solution for molecular diagnostics.
- Consolidation of quality assays for infectious-disease testing on a single, automated platform.
- Multiplexing of up to six assays from one sample in one run.
- Standardized extraction method for isolation of quality nucleic acids from a wide variety of specimen types.
- Flexible open-channel capabilities enables customization of laboratory-developed and third-party assays.
- Efficient workflow with powerful productivity due to ease of use, minimum hands-on time, maximum walkaway time, and fast turnaround time.

## One Solution— More Choice.


**Answers for life.**

# kPCR PLX Cytomegalovirus (CMV) DNA Assay

## Performance Characteristics

| Description | Value |
|---|---|
| Limit of detection (LoD) | 215 IU/mL |
| Linear range | 5.00 E2 to 1.00 E7 IU/mL |
| Clinical specificity (negative samples) | ≥95% |

## Product Specifications

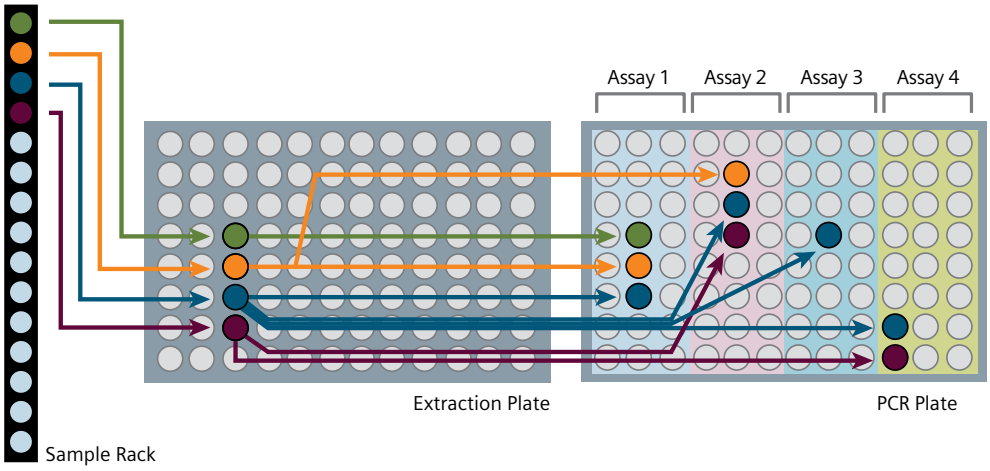
| Description | Value |
|---|---|
| Reagent storage conditions | -20°C |
| Specimen volume | 700 µL |
| kPCR PLX Universal Negative Control (UNC) | Full process negative control that is extracted and amplified along with the samples |

## Ordering Information

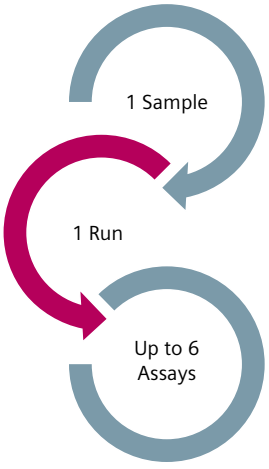
| Catalog Number | kPCR PLX Assay Menu* | Quantity |
|---|---|---|
| 10718587 | kPCR PLX Adenovirus DNA | 72 tests |
| 10718585 | kPCR PLX BK Virus (BKV) DNA | 72 tests |
| 10718580 | kPCR PLX Cytomegalovirus (CMV) DNA | 72 tests |
| 10718581 | kPCR PLX Epstein-Barr Virus (EBV) DNA | 72 tests |
| 10718582 | kPCR PLX Herpes Simplex Virus 1 and 2 (HSV) DNA | 72 tests |
| 10718584 | kPCR PLX Human Herpes Virus 6 (HHV-6) DNA | 72 tests |
| 10718586 | kPCR PLX JC Virus (JCV) DNA | 72 tests |
| 10718598 | kPCR PLX Parvovirus B19 DNA | 72 tests |
| 10718583 | kPCR PLX Varicella-Zoster Virus (VZV) DNA | 72 tests |
| 10629800 10629801 | VERSANT Sample Preparation 1.2 Reagents (Boxes 1 and 2) | 96 tests |

*kPCR PLX assays include all controls and calibrators in the same kit.
CE marked for IVD use.

**VERSANT MiPLX Software with Dynamic Protocols allows you to run 1, 2, 4, or 6 assays from one extracted sample in one run.**




**VERSANT MiPLX Software Solution**




Optimize your laboratory's workflow with the ability to run the kPCR PLX Cytomegalovirus (CMV) DNA assay along with other kPCR PLX assays from a single patient specimen.

For customer support, please contact your local technical support provider or distributor or visit **www.siemens.com/diagnostics.**

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kPCR PLX assays are manufactured by altona Diagnostics GmbH and distributed by Siemens Healthcare Diagnostics Inc.

Product availability may vary from country to country and is subject to varying regulatory requirements. Please contact your local representative for availability.

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