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kPCR PLX Parvovirus B19 DNA Assay

VERSANT kPCR Molecular System

Assay Description

The kPCR PLX Parvovirus B19 DNA assay is an in vitro diagnostic test for the detection and quantification of parvovirus B19-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

- Parvovirus B19 causes a childhood rash called fifth disease or erythema infectiosum, commonly known as slapped cheek syndrome.
- Parvovirus B19 is a major cause of a plastic crisis in patients with hemolytic anemia.
- Severe fetal complications can be observed, especially following maternal infections during the second and third trimesters.
- Three distinct genotypes of parvovirus B19 have been identified (genotypes I–III), varying by up to 15% in nucleotide identity.
- Plasma pools used in the production of anti-D immunoglobulin and plasma treated for virus inactivation are tested for levels of parvovirus B19 DNA. These plasma pools must not exceed a threshold concentration of 10 IU/μL for parvovirus B19 DNA.

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.



kPCR PLX Parvovirus B19 DNA Assay

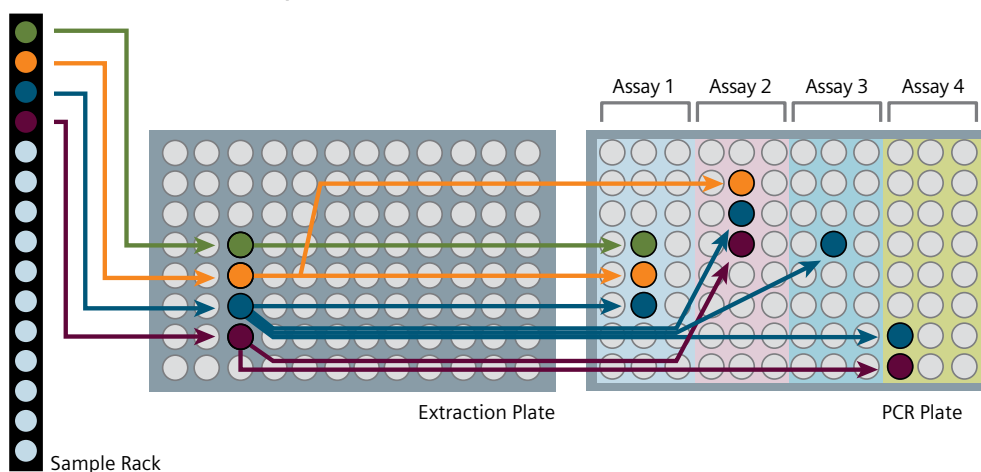
Performance Characteristics	
Description	Value
Limit of detection (LoD)	207 IU/mL
Linear range	2.50 E2 to 1.00 E6 IU/mL
Clinical specificity (negative samples)	≥95%

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

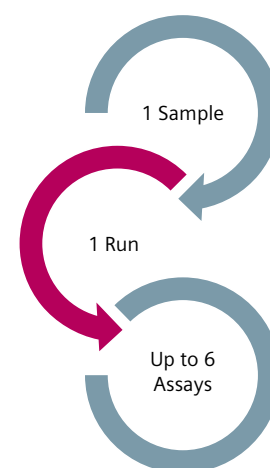
Ordering Information		
Catalog Number	kPCR PLX Assay Menu*	Quantity
10718587	kPCR PLX Adenovirus DNA	72 tests
10718585	kPCR PLX BK Virus (BKV) DNA	72 tests
10718580	kPCR PLX Cytomegalovirus (CMV) DNA	72 tests
10718581	kPCR PLX Epstein-Barr Virus (EBV) DNA	72 tests
10718582	kPCR PLX Herpes Simplex Virus 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	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 Parvovirus B19 DNA assay along with other kPCR PLX assays from a single patient specimen.

Please contact your local sales representative to learn more about the full line of our molecular assays for infectious diseases or visit siemens.com/molecular.

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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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