

**Overview****Useful For**

Diagnosing parvovirus B19 infection in plasma specimens

**Method Name**

Real-Time Polymerase Chain Reaction (PCR)/DNA Probe Hybridization

**NY State Available**

Yes

**Specimen****Specimen Type**

Plasma EDTA

**Specimen Required**

**Supplies:** Aliquot Tube, 5 mL (T465)

**Collection Container/Tube:** Lavender top (EDTA)

**Submission Container/Tube:** Aliquot Tube, 5 mL (T465)

**Specimen Volume:** 0.5 mL

**Collection Instructions:** Spin down and submit plasma in aliquot tube.

**Forms**

If not ordering electronically, complete, print, and send a [Microbiology Test Request](#) (T244) with the specimen.

**Specimen Minimum Volume**

0.3 mL

**Reject Due To**

Gross hemolysis	Reject
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**Specimen Stability Information**

Specimen Type	Temperature	Time	Special Container
Plasma EDTA	Refrigerated (preferred)	7 days	
	Frozen	7 days	

**Clinical and Interpretive**

## Clinical Information

Parvovirus B19 is a DNA virus that preferentially replicates in erythroid progenitor cells.(1) Infection with parvovirus B19 can occur at any age, but is most common early in life. Antibody prevalence ranges from 2% to 15% in children 1 to 5 years old to 30% to 60% in adults.(1) The virus is transmitted by respiratory secretions and occasionally by blood products.

Parvovirus B19 infections can be asymptomatic or produce a wide spectrum of disease ranging from erythema infectiosum (â€œfifth diseaseâ€• characterized by a classic â€œslapped cheekâ€• rash) in children to arthropathy, severe anemia, and systemic manifestations involving the central nervous system, heart, and liver depending on the immune competence of the host.(2,3) Infection with parvovirus B19 in pregnant women may cause hydrops fetalis, congenital anemia, spontaneous abortion, or stillbirth of the fetus.(4) Parvovirus B19 is also the causative agent of transient aplastic crisis and chronic aplasia usually, but not exclusively, in immunocompromised or transplant patients, and those with preexisting hematologic disorders (eg, sickle cell disease).

Most acute infections with parvovirus B19 are diagnosed in the laboratory by serologically detecting IgG- and IgM-class antibodies with enzyme-linked immunosorbent assay testing.

## Reference Values

Not applicable

## Interpretation

A positive result indicates that parvovirus B19 DNA is present in the clinical sample. However, a positive result does not differentiate between actively replicating virus, transient infection that may be asymptomatic, or the presence of remnant viral nucleic acid.

A negative result suggests the absence of parvovirus B19 infection.

## Cautions

A negative result does not necessarily indicate the absence of parvovirus B19 infection. False-negative results may be due to the virus being present at levels below the limit of detection for this assay, or to inhibitory substances that may be present in the specimen.

This assay has only been validated for the detection of genotype 1 parvovirus B19 and its ability to detect the less common genotypes 2 and 3 is unknown.

## Supportive Data

The following data supports the use of this assay for clinical testing.

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Accuracy/Diagnostic Sensitivity and Specificity:

Results from this real-time PCR assay on the LightCycler (LC PCR) were compared to a Centers for Disease Control and Prevention (CDC) PCR-based assay on tissue biopsy specimens of temporal artery. Using the CDC PCR method as the gold standard, the diagnostic sensitivity and specificity for detection of parvovirus B19 was 97%.

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Supplemental Data:

To supplement the above data, 30 negative cerebrospinal fluid, body fluids, and tissues and 45 negative blood

specimens were spiked with parvovirus B19-positive control plasmid at the limit of detection (LoD) (10-20 targets/microliter). The 30 spiked specimens (45 bloods) were run in a blinded manner along with 30 negative (nonspiked) specimens (45 bloods). Results showed 97% to 100% of the spiked specimens were positive and 100% of the nonspiked specimens were negative.

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Analytical Sensitivity/LoD:

The lower LoD of this assay is 10 to 20 targets/microliter in sample matrix.

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Analytical Specificity:

No PCR signal was obtained with extracts of 11 viral and bacterial isolates that may cause symptoms similar to infection with parvovirus, including herpes simplex virus, varicella-zoster virus, cytomegalovirus, human herpesvirus-6, -7, and -8.

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Precision:

Interassay precision was 100% and intra-assay precision was 97%.

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Reference Range:

Although the reference range is typically "negative" for this assay, this assay may detect viremia in asymptomatic individuals or remnant viral nucleic acid. However, this assay is only to be used for patients with a clinical history and symptoms consistent with parvovirus B19 infection, and must be interpreted in context of clinical picture. This test should not be used to screen asymptomatic patients.

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Reportable Range:

This is a qualitative assay, and results are reported as either negative or positive for targeted parvovirus B19.

### **Clinical Reference**

1. Heegaard ED, Brown KE: Human parvovirus B19. Clin Microbiol Ref 2002;15:485-505
2. Bultmann BD, Klingel K, Soltar K, et al: Fatal parvovirus B19 associated myocarditis clinically mimicking ischemic heart disease: an endothelial cell-mediated disease. Hum Pathol 2003;34:92-95
3. Rerolle JP, Helal I, Morelon E: Parvovirus B19 infection after renal transplantation. Nephrologie 2003;24:309-315
4. Chisaka H, Morita E, Yaegashi N: Parvovirus B19 and the pathogenesis of anaemia. Rev Med Virol 2003;16:347-359

## Performance

### Method Description

Viral DNA is extracted from 0.2 mL of specimen by the MagNA Pure automated instrument (Roche Applied Science). LightCycler PCR primers and probes detect target B19 DNA (nonstructural protein). The LightCycler instrument amplifies and monitors by fluorescence the development of target nucleic acid sequences after the annealing step during PCR cycling. This automated PCR system can rapidly detect (30-40 minutes) amplicon development through stringent air-controlled temperature cycling in capillary cuvettes. The detection of amplified products is based on the fluorescence resonance energy transfer (FRET) principle. For FRET product detection, a hybridization probe with a donor fluorophore, fluorescein, on the 3' end is excited by an external light source and emits light that is absorbed by a second hybridization probe with an acceptor fluorophore, LC-Red 640, at the 5' end. The acceptor fluorophore then emits a light of a different wavelength that can be measured with a signal that is proportional to the amount of specific PCR product. Melting curve analysis is performed following PCR amplification. Starting at 45 degrees C, the temperature in the thermal chamber is slowly raised to 80 degrees C and the fluorescence is measured at frequent intervals. Analysis of the PCR amplification and the probe melting curves is accomplished through the use of LightCycler software. (Soares RM, Durigon EI, Bersano JG, Richtzenhain LG: Detection of porcine parvovirus DNA by the polymerase chain reaction assay using primers to the highly conserved nonstructural protein gene, NS-1. J Virol Methods 1999;78:1-2;191-198)

### PDF Report

No

### Day(s) and Time(s) Test Performed

Monday through Friday; Varies

### Analytic Time

Same day/1 day

### Maximum Laboratory Time

5 days

### Specimen Retention Time

1 week

### Performing Laboratory Location

Rochester

## Fees and Codes

### Fees

- Authorized users can sign in to [Test Prices](#) for detailed fee information.
- Clients without access to Test Prices can contact [Customer Service](#) 24 hours a day, seven days a week.
- Prospective clients should contact their Regional Manager. For assistance, contact [Customer Service](#).

### Test Classification

This test was developed and its performance characteristics determined by Mayo Clinic in a manner consistent with CLIA requirements. This test has not been cleared or approved by the U.S. Food and Drug Administration.

### CPT Code Information

87798

**LOINC® Information**

Test ID	Test Order Name	Order LOINC Value
PARVP	Parvovirus B19 PCR, P	9571-1

Result ID	Test Result Name	Result LOINC Value
56075	Parvovirus B19 By Rapid PCR	9571-1
SS008	Source	31208-2