

Overview

Useful For

Rapid qualitative detection of Epstein-Barr virus (EBV) DNA in specimens

Diagnosis of disease due to EBV

This test **should not be used** to screen asymptomatic patients.

Method Name

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

NY State Available

No

Specimen

Specimen Type

Varies

Necessary Information

Specimen source is required.

Specimen Required

Submit only 1 of the following specimens:

Specimen Type: Body fluid

Sources: Spinal, peritoneal, ascites, pericardial, pleural, thoracentesis, amniotic, or ocular

Supplies: Sarstedt Aliquot Tube, 5mL (T914)

Container/Tube:

Preferred: Sterile, screw cap, 5-mL aliquot tube

Acceptable: Sterile container

Specimen Volume: 0.5 mL

Collection Instructions: Do not centrifuge.

Specimen Type: Respiratory fluid

Sources: Bronchial washing, bronchoalveolar lavage, nasopharyngeal aspirate or washing, sputum, or tracheal aspirate

Supplies: Sarstedt Aliquot Tube, 5mL

Container/Tube:

Preferred: Sterile, screw cap, 5-mL aliquot tube

Acceptable: Sterile container

Specimen Volume: 1.5 mL

Collection Instructions: Do not centrifuge.

Specimen Type: Swab

Sources: Eye and upper respiratory (nasal, throat)

Supplies:

-Culturette (BBL Culture Swab) (T092)

-M4-RT (T605)

Container/Tube: Multimicrobe media (M4-RT) and Eswabs

Collection Instructions: Place swab back into multimicrobe media (M4-RT, M4 or M5)

Specimen Type: Bone marrow

Container/Tube: Lavender top (EDTA)

Specimen Volume: 0.5 mL

Additional Information: Clotted specimens will be rejected.

Specimen Type: Tissue

Sources: Brain, colon, kidney, liver, lung, cornea, etc.

Supplies: M4-RT (T605)

Container/Tube:

Preferred: Multimicrobe medium (M4-RT)

Acceptable: Sterile container containing 1 to 2 mL of sterile saline or multimicrobe medium (M4-RT, M4 or M5)

Specimen Volume: Entire collection

Collection Instructions: Submit only fresh tissue

Specimen Minimum Volume

Fluids: 0.3 mL; Respiratory Specimens: 1 mL; Tissue: 2 x 2-mm biopsy; Swab: See Specimen Required

Reject Due To

<p>Calcium alginate-tipped swab Wood swab Transport swab containing gel Formalin-fixed and paraffin-embedded tissues Heat inactivated specimens</p>	<p>Reject</p>
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Specimen Stability Information

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

Clinical & Interpretive

Clinical Information

Epstein-Barr virus (EBV) is the causative agent of infectious mononucleosis, Burkitt lymphoma, and in Southern China, nasopharyngeal carcinoma. EBV-associated central nervous system (CNS) disease is most frequently associated with primary CNS lymphoma in patients with AIDS. In addition, CNS infection associated with the detection of EBV DNA can be seen in immunocompetent patients.

Reference Values

Negative

Reference values apply to all ages.

Interpretation

Detection of Epstein-Barr virus (EBV) DNA in cerebrospinal fluid (CSF) supports the clinical diagnosis of central nervous system (CNS) disease due to the virus. EBV DNA is not detected in CSF from patients without CNS disease caused by this virus.

Cautions

A negative result does not eliminate the possibility of Epstein-Barr virus (EBV) infection of the central nervous system.

This assay may detect viremia or viral shedding in asymptomatic individuals. However, this assay is only to be used for patients with a clinical history and symptoms consistent with EBV infection and must be interpreted in the context of the clinical picture.

Supportive Data

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

Epstein-Barr Virus:

Accuracy/Diagnostic Sensitivity and Specificity:

To assess the accuracy of the Epstein-Barr virus (EBV) laboratory-developed test (LDT), known previously positive clinical specimens (20 positive, 30 negative) were tested, and the results compared to those of a laboratory-developed reference polymerase chain reaction (PCR) method.

EBV LDT		EBV reference LDT	
		Positive	Negative
	Positive	20	0

	Negative	0	30
	Total	20	30

Sensitivity (95% CI): 100% (81-100)

Specificity (95% CI): 100% (86-100)

Analytical Sensitivity/Limit of Detection:

The 95% limit of detection (LOD) for this assay is less than 10 targets per microliter using plasmid and whole virus spiked into matrix. The LOD was confirmed in each matrix type that is accepted for testing with this assay.

Analytical Specificity:

No PCR signal was obtained from extracts of 40 bacterial and viral isolates that could cause similar symptoms including herpes simplex virus 1 and 2; cytomegalovirus; varicella zoster virus; and human herpes virus (HHV) 6, HHV 7, and HHV 8.

Precision:

Interassay precision was 100%, and intraassay precision was 100%.

Reportable Range:

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

Clinical Reference

1. Tachikawa N, Goto M, Hoshino Y, et al: Detection of *Toxoplasma gondii*, Epstein-Barr virus, and JC virus DNAs in the cerebrospinal fluid in acquired immunodeficiency syndrome patients with focal central nervous system complications. *Intern Med.* 1999;38(7):556-562. doi: 10.2169/internalmedicine.38.556
2. Antinori A, Cingolani A, De Luca A, et al: Epstein-Barr virus in monitoring the response to therapy of acquired immunodeficiency syndrome-related primary central nervous system lymphoma. *Ann Neurol.* 1999;45(2):259-261
3. Cingolani A, De Luca A, Larocca LM, et al: Minimally invasive diagnosis of acquired immunodeficiency syndrome-related primary central nervous system lymphoma. *J Natl Cancer Inst.* 1998;90(8):364-369. doi: 10.1093/jnci/90.5.364
4. Niller HH, Wolf H, Minarovits J: Regulation and dysregulation of Epstein-Barr virus latency: implications for the development of autoimmune disease. *Autoimmunity.* 2008;41(4):298-328. doi: 10.1080/08916930802024772
5. Studahl M, Hagberg L, Rekvad E, Bergstrom T: Herpesvirus DNA detection in cerebrospinal fluid: difference in clinical presentation between alpha-, beta-, and gamma-herpes viruses. *Scand J Infect Dis.* 2000;32(3):237-248. doi: 10.1080/00365540050165857
6. Lau AH, Soltys K, Sindhi RK, Bond G, Mazariegos GV, Green M: Chronic high Epstein-Barr viral load carriage in pediatric small bowel transplant recipients. *Pediatr Transplant.* 2010;14(4):549-553. doi: 10.1111/j.1399-3046.2009.01283.x
7. Fugl A, Andersen CL: Epstein-Barr virus and its association with disease - a review of relevance to general practice. *BMC Fam Pract.* 2019 May 14;20(1):62. doi: 10.1186/s12875-019-0954-3

Performance

Method Description

Viral nucleic acid is extracted by the MagNA Pure automated instrument (Roche Applied Science) from clinical specimens. Primers are directed to the target gene (latent membrane protein). The LightCycler instrument amplifies and monitors by fluorescence the development of target nucleic acid sequences after the annealing step during polymerase chain reaction (PCR) cycling. This is an automated PCR system that 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 probe melting curves is accomplished through the use of LightCycler software.(Unpublished Mayo method)

PDF Report

No

Day(s) Performed

Monday through Saturday

Report Available

2 to 3 days

Specimen Retention Time

14 days

Performing Laboratory Location

Jacksonville

Fees & 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 account representative. For assistance, contact [Customer Service](#).

Test Classification

This test was developed using an analyte specific reagent. Its performance characteristics were determined by Mayo Clinic in a manner consistent with CLIA requirements. This test has not been cleared or approved by the US Food and Drug Administration.

CPT Code Information

87798

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
LEBV	Epstein-Barr Virus PCR	23858-4

Result ID	Test Result Name	Result LOINC® Value
SRC67	Specimen Source	31208-2
81239	Epstein-Barr Virus PCR	23858-4