

EBV

Epstein-Barr Virus by PCR – Quantitative

GA Test Code	6111
Method	Quantitative Real-Time Polymerase Chain Reaction (qPCR)
Specimens	<p>Whole Blood (EDTA or ACD): 5.0 mL (3.0 mL), ambient (4 days), refrigerated (7 days).</p> <p>CSF: 1.0 mL (0.2 mL), refrigerated (7 days) or frozen (indefinite).</p> <p>Plasma (EDTA, ACD, or PPT): 3.0 mL (1.0 mL), separated/centrifuged within 6 hours, refrigerated or frozen (<i>do not freeze in PPT</i>). If storing longer than 24 hours, store frozen.</p> <p>Serum: 2.0 mL (1.0 mL), refrigerated (7 days) or frozen (indefinite).</p> <p>Bone Marrow: 3.0 mL (2.0 mL), refrigerated (up to 7 days).</p> <p>Other Samples: Please contact GA for questions about other specimens.</p>
Causes for Rejection	Quantity not sufficient (QNS) for analysis; time and/or temperature instructions not followed; blood in heparin; plasma frozen in PPT.
Reference Range	Not Detected (< 200 copies/mL)
Quantitative Range	200 to 5,000,000 EBV DNA copies/mL
Turnaround Time	Same or Next Day
CPT Code	87799

Description

This test was developed and its performance characteristics determined by Genetic Assays. It has not been cleared nor approved by the U.S. FDA. The FDA has determined that such clearance or approval is not necessary. This test is used for clinical purposes. It should not be regarded as investigational or for research. Genetic Assays is certified under CLIA as qualified to perform high-complexity testing. Epstein-Barr Virus (EBV) DNA quantification is based upon the real-time PCR amplification and detection of EBV genomic DNA. A patient value of less than 200 EBV DNA copies/mL indicates that the viral load is below the quantitative limit of this assay, but does not indicate that the patient is not infected with EBV.

Clinical Utility

EBV is a herpes virus that has been implicated in the development of lymphoid malignancies such as Burkitt's lymphoma and Hodgkin's disease. Clinical results suggest that whole blood EBV viral loads may represent an important functional measure of immunosuppression in solid-organ transplant patients. Recent studies have also demonstrated a direct relationship between EBV viral load and the risk of developing post transplant lymphoproliferative disorder (PTLD). EBV DNA has been detected in cell-free fractions (plasma or serum) of patients with PTLD, Hodgkin's, and AIDS-related lymphomas. Conventional PCR-based tests allow only semi-quantitative measures of viral DNA. Real-time PCR provides the highly sensitive, specific and quantitative determination of EBV DNA, which can be an important tool for early diagnosis of disease as well as a method to monitor response to treatment. Real-time PCR has a greater dynamic range in which samples can be analyzed quantitatively without subsequent dilution. Furthermore, clinical cancer research has found that most nasopharyngeal cancer patients have the EBV genome in their tumor tissues. The use of PCR makes it possible to detect small amounts of EBV DNA in a wide array of tissues, thus making it a non-invasive form of tumor detection that results in higher patient survival rates.

Lei KL, Chan LY, Chan WY, Johnson PJ and Lo YM, Diagnostic and prognostic implications of circulating cell-free Epstein-Barr virus DNA in natural killer/T-cell lymphoma. *Clin Cancer Res.* 2002 Jan;8(1):29-34.

Jabs WJ, Hennig H, Kittel M, Pethig K, Smets F, Bucsky P, Kirchner H, Wagner HJ. Normalized quantification by Real-time PCR of Epstein-Barr virus load in patients at risk for post transplant lymphoproliferative disorders. *J Clin Microbiol.* 2001 Feb; 39 (2):564-9.

Le et al. A Comparison Study of Different PCR Assays in Measuring Circulating Plasma EBV DNA Levels in Patients with Nasopharyngeal Carcinoma. *Clin Cancer Res.* 2005;11(16):5700-5707.

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