

GenePath Dx Epstein-Barr virus (EBV) qPCR test kit

Real time detection and quantification of Epstein-Barr virus

Epstein-Barr virus (EBV), also known as human herpesvirus 4, is a gamma herpes virus that occurs only in humans. The GenePath Dx EBV assay is intended for the diagnosis and viral load quantification of EBV to aid in the management of patients who have undergone solid organ transplant, are immuno-compromised, patients having infectious mononucleosis or flu-like symptoms and patients with EBV related malignancies such as Burkitt's Lymphoma and nasopharyngeal carcinoma.

Salient Features:

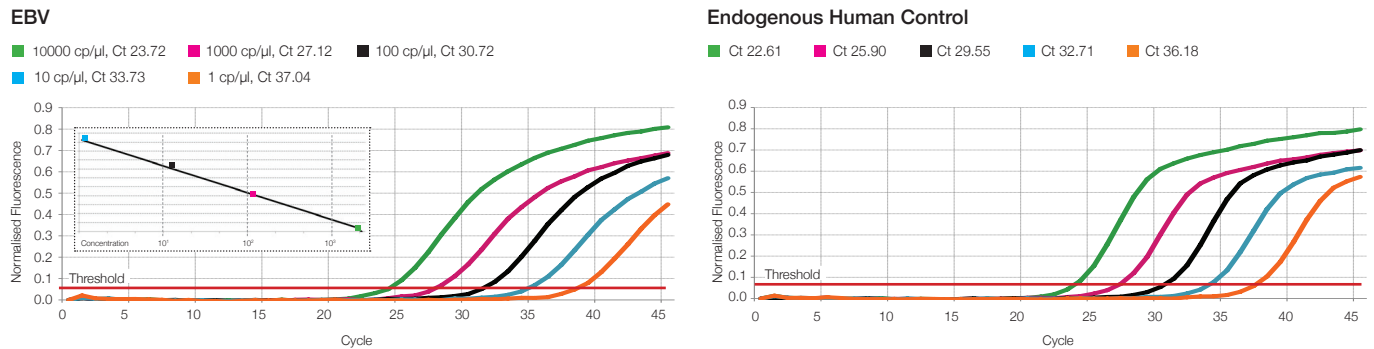
- Highly sensitive and specific assay for the real time detection and quantification of Epstein-Barr virus (EBV)
- Two EBV target genes multiplexed into a single channel
- Presence of an endogenous human control gene allows process control through sample preparation
- Short run time of less than 60 minutes
- Two channel assay with broad instrument compatibility (kit validated on the Qiagen Rotor-Gene Q, Bio-Rad CFX96, Bio-Rad Opus, Roche LightCycler II 480 and Thermo/ABI QuantStudio5, 7500 FAST and StepOne instruments; fluorophores compatible with most real time thermocyclers)

Performance Characteristics:

1. Analytical Sensitivity:

The analytical sensitivity of the *GenePath Dx Epstein-Barr virus (EBV) qPCR assay* has shown to reproducibly go down to **1 copy/μL** (5 copies/PCR reaction). When paired with a standard sample preparation protocol using silica column or magnetic beads, the analytical sensitivity of the test was shown to reproducibly go below **175 copies/mL** in blood (when eluted in 35 μL).

Analytical sensitivity of the *GenePath Dx EBV qPCR kit* using EBV standards of known concentrations is shown below:



2. Analytical Specificity:

Laboratory (wet lab)* analysis shows that the test and its component assays are highly specific to EBV and demonstrate no cross reactivity to or interference from closely related or commonly encountered pathogens or commensals.

*Organisms tested in the laboratory for cross reactivity and interference: Human metapneumovirus (hMPV), Human Enterovirus, Human RSV, Human Parvovirus, Human Cytomegalovirus (CMV), hCov (HKU1, NL63, 229E), Influenza A H3N2, Influenza B, Influenza A H1N1 pdm09, SARS, MERS, Hepatitis C virus (HCV), Hepatitis B virus (HBV), BKV, Chikungunya virus, *Streptococcus salivarius*, *Candida albicans*, *Streptococcus sp.*, *Mycobacterium tuberculosis* (H37Rv), *Haemophilus influenzae* type b.

This kit is intended for use by experienced clinical laboratory personnel specifically instructed and trained in the techniques of real-time PCR and *in vitro* diagnostic procedures for infectious pathogens.

For more information, please contact kit.sales@genepathdx.com.



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