

Human Papillomavirus (HPV) Type 16 with Type 18, 31, 33, and 35 Reflex, Droplet Digital PCR, Blood

Test ID: DHPVR

Useful for:

Aid in the diagnosis of cancers caused by human papillomavirus (HPV) high-risk genotypes 16, 18, 31, 33, and 35.

Pre-diagnostic screening (ie, prior to confirmation of an HPV-related cancer through traditional biopsy).

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

Reflex Tests:

Test ID	Reporting Name	Available Separately	Always Performed
DHPVB	HPV-18/31/33/35, cfDNA, ddPCR, B	Yes	No

Note: If testing is positive for the human papillomavirus (HPV)-16 genotype, no further testing is performed. If negative for HPV-16, reflex testing for the less frequently encountered HPV-18, -31, -33 and -35 genotypes is performed at an additional charge.

Methods:

Droplet Digital Polymerase Chain Reaction (ddPCR)

Reference Values:

Not detected

Specimen Requirements:

Supplies:	Streck Tan Top Tube Kit (T715)
Container/Tube:	Streck Cell-Free DNA blood collection kit
Specimen Volume:	Two 10-mL Streck Cell-Free DNA blood collection tubes
Additional Information:	Only blood collected in Streck Cell-Free DNA tubes will be accepted for analysis.
Minimum Volume:	One 10 mL Streck Cell-Free DNA blood collection tube

Specimen Stability Information:

Specimen Type	Temperature	Time
Whole blood	Ambient (preferred)	7 days
	Refrigerated	7 days

Cautions:

This assay only detects genetic fragments of the following human papillomavirus (HPV) genotypes: 16, 18, 31, 33 and 35.

This assay will not detect other HPV genotypes.

This assay will not specify an anatomic location or source of detectable levels of HPV.

A result of "Not Detected" does not necessarily eliminate the possibility of HPV infection, or a tumor caused by HPV. Serial measurement of HPV in platelet poor plasma may be recommended based on clinical presentation.

This assay should only be used for patients with a clinical history and/or symptoms consistent with a confirmed or suspected HPV-related tumor.

Results must be interpreted in the context of the patient's clinical picture.

Variants within the HPV E2, E6 and E7 gene regions targeted by this assay may affect primer and/or probe binding, resulting in the under quantitation of viral fragments or failure to detect the presence of viral fragments. The assay attempts to mitigate this risk by inclusion of multiple gene target regions.

NY State Information:

NY State Available: No (pending review)

CPT Code:

87799

Day(s) Performed: Varies

Report Available: 5 to 10 days

Questions

Contact James Conn, Laboratory Resource Coordinator at 800-533-1710.