



Report Date: 5/23/2024 2:49 PM

Patient Name: TEST PATIENT
Case Number: EPV2024-0001301

Sex at Birth: Male
DOB: 12/11/1955
Sample: Peripheral Blood
Collected Date: 05/20/2024
Indication: Screening

Result:

Abnormal Methylation Signal Detected

Interpretation:

Cancer-associated methylation biomarkers are identified in this patient sample. While this finding is often associated with invasive carcinoma, precancerous conditions and some benign conditions may show similar methylation patterns. This test is intended as a screening tool. A positive test should not be interpreted as a definitive diagnosis of cancer. Correlation with clinical findings, diagnostic imaging such as PET-CT, and further laboratory testing may be of benefit. The ordering healthcare provider is welcome to contact our pathologists for consultation.

Digitally Signed by:

Joshua Routh, M.D.
DIGITAL SIGNATURE 5/23/2024 2:49 PM

Methodology

This test detects circulating fragments of DNA with hypermethylation at 10 specific genomic locations. Hypermethylation at these loci is observed in multiple cancers. The test uses quantitative polymerase chain reaction (qPCR) to detect hypermethylated DNA following bisulfite conversion. In a validation study, this test was positive in 65% of patients known to have cancer and negative in >98% of patients with no known history of cancer.

This test is intended to be used as a screening tool to detect occult cancer in patients with no symptoms or history of cancer. A positive result on this test should be followed up by a confirmatory workup which may include a detailed clinical history, physical examination, imaging, and tissue biopsy. A negative result does not completely rule out cancer. Some cancers do not shed tumor DNA and may not be detected by cfDNA assays. Some cancers are not associated with methylation in the regions tested by this assay and will not reliably be detected by this assay. For more information regarding the performance of this assay visit <http://www.epi-seek.com>

This test was developed and its performance characteristics determined by Precision Epigenomics. It has not been cleared or approved by the US Food and Drug Administration. This test was performed in a CLIA certified laboratory and is intended for clinical purposes.