

Client: Example Client ABC123
123 Test Drive
Salt Lake City, UT 84108
UNITED STATES

Physician: Doctor, Example

Patient: Patient, Example

DOB [REDACTED]
Gender: Male
Patient Identifiers: 01234567890ABCD, 012345
Visit Number (FIN): 01234567890ABCD
Collection Date: 00/00/0000 00:00

Epi proColon
ARUP test code 2013906

Epi proColon Result

Positive *

Methylated Septin 9 was detected.

This result has been reviewed and approved by Deepika Sirohi,
M.D.

H=High, L=Low, *=Abnormal, C=Critical

BACKGROUND INFORMATION: Epi proColon Result

The Epi proColon test detects the presence of methylated Septin 9 DNA in blood plasma and is FDA-approved. However, a positive Epi proColon test result is not confirmatory evidence for colorectal cancer (CRC). Patients with a positive Epi proColon test result should be referred for diagnostic colonoscopy. A negative Epi proColon test result does not guarantee absence of cancer. Patients with a negative Epi proColon test result should be advised to continue participating in a recommended CRC screening program according to screening guidelines. (Screening and surveillance for the early detection of colorectal cancer and adenomatous polyps, 2008: a joint guideline from the American Cancer Society, the US Multi-Society Task Force on Colorectal Cancer, and the American College of Radiology. NGC:007214. Screening for Colorectal Cancer: US Preventive Services Task Force Recommendation Statement. US Preventive Services Task Force, Bibbins-Domingo K, Grossman DC, Curry SJ, Davidson KW, Epling JW Jr, Garcia FA, Gillman MW, Harper DM, Kemper AR, Krist AH, Kurth AE, Landefeld CS, Mangione CM, Owens DK, Phillips WR, Phipps MG, Pignone MP, Siu AL. JAMA. 2016 Jun 21;315(23):2564-75.)

CLINICAL SENSITIVITY: Two clinical trials with three cohorts were conducted with a sensitivity of 68.2 percent, 73.3 percent, and 72.2 percent and specificity of 78.8 percent, 81.5 percent, and 80.8 percent respectively.

METHODOLOGY: Circulating DNA is extracted, undergoes bisulfite conversion, and then purified. The DNA is analyzed by a Real-Time PCR method to simultaneously detect both methylated Septin 9 and an internal control gene. Each specimen is analyzed in triplicate PCR reactions in order to maximize sensitivity.

LIMITATIONS: Methylation at locations other than those encompassed by the primers and probes will not be detected. The Epi proColon test results should be used in combination with the physician's assessment and individual risk factors in guiding patient management. Positive test results have been observed in healthy subjects, in the elderly, and in patients diagnosed with chronic gastritis, lung cancer, and in pregnant women.

The Epi proColon test demonstrated inferiority to a fecal test (OC FIT-CHEK Polymedco, Inc.) for specificity, indicating that the Epi proColon test exhibited a higher rate of false positive results compared to the FIT test. The Epi proColon demonstrated non-inferiority to a fecal test for sensitivity.

For supporting information, refer to Epi proColon Instructions for Use included in the collection kit.

H=High, L=Low, *=Abnormal, C=Critical

VERIFIED/REPORTED DATES

Procedure	Accession	Collected	Received	Verified/Reported
Epi proColon Result	20-121-122797	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00

END OF CHART

H=High, L=Low, *=Abnormal, C=Critical