

MEMORANDUM

To: All Regional Medical Laboratory (RML) Clients
 From: Brittany Vaughn, MHA, MLS(ASCP)SM, Director of Clinical Operations
 Gerald C. Miller, Ph.D., Chief of Microbiology and Immunology
 Date: March 28, 2017
 Subject: **Epi proColon Blood Test for Colorectal Cancer Screening**

RML is pleased to announce the addition of the FDA approved **Epi proColon blood test for colorectal cancer (CRC) screening**. This newly available test is designed for **patients who are unwilling or unable** to be screened by recommended guidelines such as colonoscopy, sigmoidoscopy or high sensitivity fecal occult blood testing (FIT). Epi proColon is not intended to replace CRC screening by these recommended methods but instead provides an additional testing option for unwilling or unable patients who are defined as having elevated risk for developing CRC based on previous history of colorectal polyps, CRC or related cancers, inflammatory bowel disease (IBD), chronic ulcerative colitis (CUC), Crohn's disease, or familial adenomatous polyposis (FAP).

The Epi proColon test is a **qualitative in vitro diagnostic blood test which detects methylated Septin 9 DNA**, a marker associated with CRC. This test has been reported to exhibit a **higher rate of false positive** results when compared to the **FIT test**; however, the **sensitivity is comparable**. The Epi proColon test is **not confirmatory for the presence of CRC**; thus patients with a positive Epi proColon test should be referred for diagnostic colonoscopy. A negative result indicates the absence of methylated Septin 9 DNA, and patients with a negative Epi proColon test should be advised to continue participating in a routine CRC screening program which includes recommended screening methods.

Test name: Epi proColon
Test code: 6904831
CPT code: 81327
LOINC: 65810-4
Expected turnaround time: 7-10 days

Specimen requirements:

Specimen Volume (min)	Specimen Type	Specimen Container	Transport Environment
3.5 mL	Plasma	Lavender (K ₂ EDTA)	Frozen

- Centrifuge and remove plasma ASAP or within 4 hours of collection.
- Centrifuge for 12 min at 1350 ± 150 rcf. Transfer the plasma to a 15 mL conical tube.
- Centrifuge for an additional 12 minutes at 1350 ± 150 rcf. Ensure a minimum of 3.5 mL of plasma is obtained following centrifugation.
- Transfer entire plasma aliquot to a freezable specimen transport tube. Submit to the laboratory frozen.

Due to the stringent specimen processing requirements, RML requests patients present to one of the following Patient Service Centers for collection:

- Siegfried PSC located on the 5th Floor of St. John Medical Center in Tulsa, OK
- OKC Royal Avenue PSC located at 4229 Royal Ave., Suite 100, Oklahoma City, OK 73108
- Bartlesville B2 PSC located at 3400 SE Frank Phillips, Suite 105, Bartlesville, OK 74006

Please contact Brittany Vaughn, MHA, MLS(ASCP)SM, Director of Clinical Operations or Gerald C. Miller, Ph.D., Chief of Microbiology and Immunology at 918-744-2553 with questions regarding these updates.