

Patient: PtOne PtTwo

DOB: DDMmmYYYY

Sex: Male



Ordering Provider: OOne OPTwo

Provider Phone #: (123) 456 7890

Order ID: 123456ABCP

Specimen Received: DDMmmYYYY HH:MM CT

Specimen type: Stool

Original Report Date: DDMmmYYYY HH:MM CT

Specimen Collected: DDMmmYYYY

Specimen source: per rectum

TestResult:NEGATIVE

ANEGATIVE ColoSense® result indicates a low likelihood that colorectal cancer (CRC) and/or an advanced adenoma (precancerous lesion) is present. Patients with a NEGATIVE ColoSense result are advised to continue participating in a colorectal cancer screening program. The normal value for this test is NEGATIVE.

The performance of ColoSense has been established in a prospective cross-sectional clinical study of 7,763 adults 45 years of age or older with average risk of colorectal neoplasia who were screened with both ColoSense and a colonoscopy. The study showed sensitivity of 93% for CRC and 45% for advanced adenomas relative to a screening colonoscopy and a specificity of 88% for no lesions on a colonoscopy.

ColoSense has been approved for use by the U.S. Food and Drug Administration (FDA).

Intended Use / Indication For Use: ColoSense is intended for the qualitative detection of colorectal neoplasia-associated RNA markers and for the presence of occult hemoglobin in human stool. ColoSense is a single-site test performed at Geneoscopy, Inc.

A positive ColoSense result may indicate the presence of colorectal cancer (CRC), advanced adenoma (AA), or serrated precancerous lesions (SPL), and should be followed by a colonoscopy. ColoSense is indicated as a screening test for adults, 45 years of age or older, who are at typical average risk for developing CRC. ColoSense is not a replacement for diagnostic colonoscopy or surveillance colonoscopy in high-risk individuals.

Warnings and Precautions: ColoSense may produce a false negative (negative ColoSense result with findings of CRC or advanced adenomas on diagnostic colonoscopy) or false positive result (positive ColoSense result with no findings of CRC or advanced adenomas on diagnostic colonoscopy). A negative ColoSense result does not guarantee the absence of CRC or advanced adenomas. A positive ColoSense result does not guarantee the presence of CRC or advanced adenomas.

The current ColoSense screening interval is every 3 years per manufacturer recommendation or by other guideline bodies if ColoSense is included. Additional description of ColoSense warnings, precautions, and contraindications can be found at colosense.com/risk-information.

IVD

For In-Vitro Diagnostic Use.

Rx Only Prescription Use Only

Testing performed at: Geneoscopy, Inc.

CLIA ID: 26D2253457 | CAP #: 9101351

Laboratory Director: Erica Barnell, MD, PhD, HCLD

Electronically approved on DDMmmYYYY HH:MM CT by XX.



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