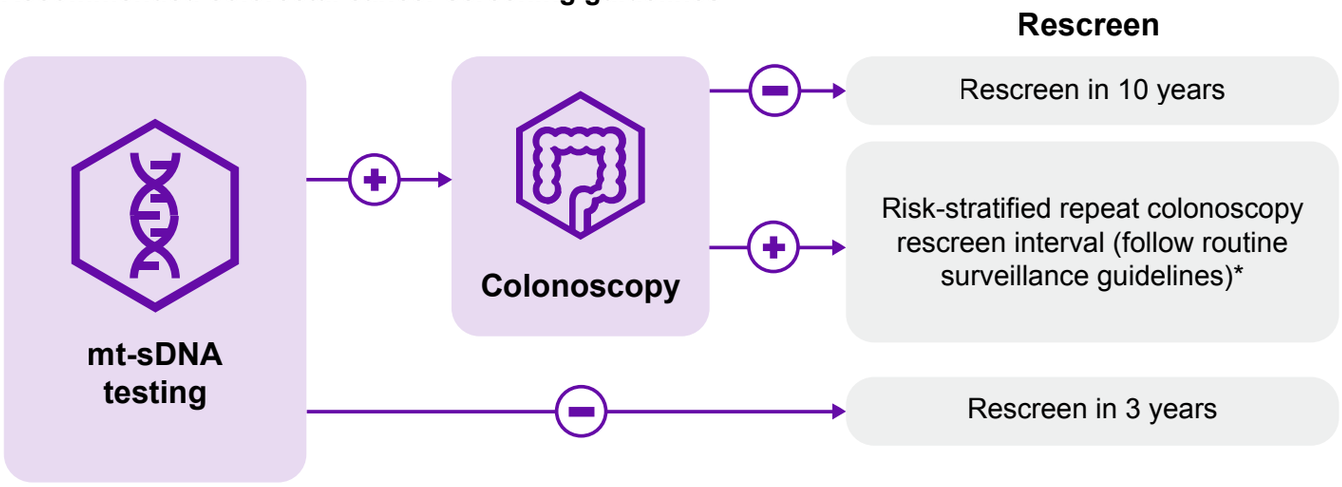
Discordant Results With the Cologuard® (mt-sDNA) Products

Discordant results: When patients receive a positive mt-sDNA test result and a negative follow-up colonoscopy result.[1]

WHAT SHOULD MY PATIENT DO IF THEY RECEIVE DISCORDANT RESULTS?

Recommended colorectal cancer screening guidelines[2-5]



Asymptomatic patients with a positive mt-sDNA result and a negative high-quality colonoscopy do not need additional testing.[3,†]

⊕ Positive test result ⊖ Negative test result

WHAT ARE THE CLINICAL CONCERNS FOR A PATIENT WITH DISCORDANT RESULTS?

Discordant results are <u>not</u> influenced by:

Aerodigestive (pulmonary and digestive tract) cancers[6]:

- Aerodigestive cancer incidence was not statistically different between individuals with positive or negative mt-sDNA results followed by a negative (clean) colonoscopy, when followed for >5 years

Other cancers or conditions[7,8]:

- Cross-reactivity causes a minor increase in test positivity (~2 to 8 potential positives per 10,000 screened individuals) and does not significantly contribute to discordant results

Blood from the upper gastrointestinal (GI) tract[5,9]:

- The hemoglobin assay of the mt-sDNA test only targets the protein portion of undigested human hemoglobin; it is unlikely that any hemoglobin detected by the test is from upper GI sources

Disclaimer: Cologuard products are intended to screen adults 45 and older at average risk for colorectal cancer. Rx only. This document is not for promotional use.

*Rescreen intervals range from 1 to 10 years depending on initial colonoscopy findings and related colorectal cancer risk.
†Additional testing means upper endoscopy, CT scan of the abdomen, or repeat colonoscopy at an interval shorter than the recommended repeat screening interval (unless indicated by other symptoms or laboratory testing).
CT: computed tomography; **GI:** gastointestinal; **mt-sDNA:** multi-target stool DNA.

1. Butterly LF, et al. *Am J Gastroenterol.* 2024;119(11):2215-2223. 2. Rex DK, et al. *Am J Gastroenterol.* 2017;112(7):1016-1030. 3. Shaukat A, et al. *Am J Gastroenterol.* 2021;116(3):458-479. 4. Gupta S, et al. *Gastrointest Endosc.* 2020;91(3):463-485.e5. 5. Wolf AMD, et al. *CA Cancer J Clin.* 2018;68(4):250-281. 6. Berger BM, et al. *Clin Gastroenterol Hepatol.* 2020;18(4):864-871. 7. FDA. Cologuard summary of safety and effectiveness data. June 12, 2013. Accessed March 18, 2025. https://www.accessdata.fda.gov/cdrh_docs/pdf13/p130017b.pdf 8. Cologuard Plus Clinician Brochure. Exact Sciences Corporation. Madison, WI. 9. Imperiale TF, et al. *N Engl J Med.* 2014;370(14):1287-1297.

Learn more about colorectal cancer screening and discordant results at Exact Academy.

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