

BLUE-C: A PIVOTAL CLINICAL TRIAL

One of the largest, most robust clinical trials to assess the performance of a screening test for colorectal cancer, BLUE-C aims to set a new bar for non-invasive screening tests.

STUDY DESIGN

- BLUE-C is a rigorous, multi-center, prospective study of more than 20,000 adults 40 years of age and older. The trial is designed to evaluate the **next-generation Cologuard®** screening test.¹
- The robust study was designed to evaluate next-generation Cologuard, a multi-target stool DNA (mt-sDNA) test that uses novel biomarkers to detect both altered DNA and hemoglobin in the stool. The study will compare mt-sDNA to:
 - **Colonoscopy** as the reference standard
 - **FIT**, a fecal immunochemical test that detects hemoglobin in the stool
 - The study also included blood collection for later evaluation of a **blood-based screening test** being developed by Exact Sciences
- Exact Sciences recruited a study population that closely reflects the racial and ethnic diversity of the U.S. population.²

STUDY ENDPOINTS

- The primary objective is to assess the sensitivity and specificity for CRC of the next-generation mt-sDNA screening test, using colonoscopy as the reference method.
- The secondary outcome measures include:
 - Sensitivity for advanced precancerous lesions (APLs)
 - Sensitivity for CRC compared to FIT
 - Sensitivity for APLs compared to FIT
 - Specificity for no colorectal neoplastic findings

SENSITIVITY

refers to the ability of a test to correctly identify the people with cancerous or pre-cancerous cells. A high degree of sensitivity means that fewer illnesses are missed.³

SPECIFICITY

refers to the ability of a test to correctly identify people without cancerous or pre-cancerous cells. High levels of specificity mean a low number of false positives.⁴

For more information on the relationship between sensitivity and specificity, [watch this short video](#).

NEXT-GENERATION COLOGUARD is a multi-target stool DNA test built on a decade of knowledge with Cologuard, using novel methylation and protein markers designed to detect cancer and precancer. Exact Sciences partnered with Mayo Clinic throughout the discovery phase to explore hundreds of biomarkers and determine promising candidates. From those, Exact Sciences conducted numerous validation studies to select the optimal biomarkers for evaluation.

With almost three decades of experience, Exact Sciences has been a pioneer in the field of colorectal cancer prevention and detection – unparalleled in its deep understanding of colorectal cancer. As the maker of Cologuard, Exact Sciences is determined to further advance technology, working to improve the patient experience, increase test accuracy, and catch cancer and pre-cancers earlier to substantially reduce patient suffering.

References

[1] Clinical validation of an optimized multi-target Stool DNA (mt-sDNA 2.0) Test, for Colorectal Cancer Screening “BLUE-C.” ClinicalTrials.gov identifier NCT04144738. Last post February 23, 2023. Accessed June 15, 2023. <https://clinicaltrials.gov/ct2/show/NCT04144738>

[2] Internal Data on File. Exact Sciences Corporation. Madison, WI.

[3] National Cancer Institute. NCI's dictionary of cancer terms. Accessed June 15, 2023. <https://www.cancer.gov/publications/dictionaries/cancer-terms/def/sensitivity>

[4] National Cancer Institute. NCI's dictionary of cancer terms. Accessed June 15, 2023. <https://www.cancer.gov/publications/dictionaries/cancer-terms/def/specificity>