

BLUE-C STUDY TOP-LINE FINDINGS

ABOUT THE BLUE-C STUDY

BLUE-C is a prospective multi-center study (NCT04144738) of more than 20,000 adults 40 years of age and older. The trial was designed to evaluate the performance of our next-generation Cologuard® test (multi-target stool DNA or mt-sDNA). It is one of the largest colorectal cancer screening trials ever conducted, and the study population reflects the racial and ethnic diversity of the United States according to the 2020 census.

SPECIFICITY

Describes how well a test can correctly identify people **without** cancer or pre-cancer

91%

Specificity - including non-advanced findings

specificity including non-advanced findings includes colonoscopy results that were negative for cancer or advanced precancer upon histopathological review

93%

Specificity - including no findings

specificity including no findings includes no findings on colonoscopy and no histopathological review

SENSITIVITY

Describes how well a test can correctly identify people **with** cancer or pre-cancer

94%

Cancer

75%

High-grade dysplasia

high-grade dysplasia includes carcinoma in situ and stage 0 cancer

43%

Advanced precancer

	Cologuard in DeeP-C study ¹	Next-gen Cologuard in BLUE-C study ²
Specificity including non-advanced findings	87	91
Specificity including no findings	90	93
Cancer Sensitivity	92	94
High-grade dysplasia sensitivity	69	75
Advanced precancer sensitivity	42	43

*DeeP-C was the FDA registrational trial for Cologuard

1. Imperiale TF et al., N Engl J Med (2014)

2. Internal data on file. Exact Sciences Corporation. Madison, WI.