

2018-10B Protocol Synopsis

Blood Collection Sub-Study of Exact Sciences Protocol 2018-10: “An Evaluation of a Multi-Target Stool DNA (mt-sDNA) Test, Cologuard, For CRC Screening in Individuals Aged 45-49 and at Average Risk for Development of Colorectal Cancer: Act Now”

NCT Number: NCT03741166

Document Date: October 16th, 2018

**BLOOD COLLECTION SUB-STUDY OF EXACT
SCIENCES PROTOCOL 2018-10: “AN
*EVALUATION OF A MULTI-TARGET STOOL DNA
(mt-sDNA) TEST, COLOGUARD, FOR CRC
SCREENING IN INDIVIDUALS AGED 45-49 AND AT
AVERAGE RISK FOR DEVELOPMENT OF
COLORECTAL CANCER: ACT NOW”***

Study Title:	Blood Collection Sub-Study of Exact Sciences Protocol 2018-10: “ <i>An Evaluation of a Multi-target Stool DNA (mt-sDNA) Test, Cologuard, for CRC Screening in Individuals Aged 45-49 and at Average Risk for Development of Colorectal Cancer: Act Now</i> ”
Study Number:	2018-10B
Version and Date:	Protocol Synopsis Version 2.0, October 16, 2018
Study Sponsor:	Exact Sciences 441 Charmany Drive Madison, WI 53719

1 PROTOCOL SYNOPSIS

Primary Objective:	The primary objective of this sub-study (2018-10B) is to collect blood samples for research use in the development of the blood-based test for colorectal cancer (CRC).
Study Design:	Prospective, multi-center, sample collection sub-study
Population:	Subjects will be men and women, 45-49 years of age, who enroll in Exact Sciences Protocol 2018-10. Up to 914 subjects will be enrolled.
Study Duration:	Duration of subject participation in this sub-study will be 1 day from enrollment to completion.
Study Procedures:	Subjects providing written informed consent to participate in the sub-study will have blood drawn.

2 STUDY DESIGN

This is an optional sub-study, for Exact Sciences Protocol 2018-10, in which blood samples will be collected for future investigations of biomarkers for CRC screening.

Subjects who consent to enroll in Exact Sciences Protocol 2018-10 will be invited to participate in this sub-study.

3 OBJECTIVES

3.1 Primary Objective

The primary objective of this sub-study is to collect blood samples for research use in the development of the blood-based test for colorectal cancer.

4 Inclusion Criteria

Subjects must meet the following criteria to be eligible for the study:

1. Subject is currently enrolled in Exact Sciences Protocol 2018-10.
2. Subject is willing and able to provide a blood sample.
3. Subject is willing and able to sign informed consent.

5 Exclusion Criteria

Subjects presenting with any of the following will not be included in the study:

1. Subject has any condition that in the opinion of the Investigator should preclude participation in the study.

APPENDIX 1.0 – STUDY SCHEDULE

Activity	Enrollment Visit
Informed Consent	X
Obtain Blood Sample	X
Adverse Event Reporting	X