



Multi-target Fecal DNA Test for  
Colorectal Cancer Screening

**Sensitivity for  
colorectal cancer  
is 96.08%**

**Sensitivity for  
advanced  
precancerous  
lesions is 52.50%**

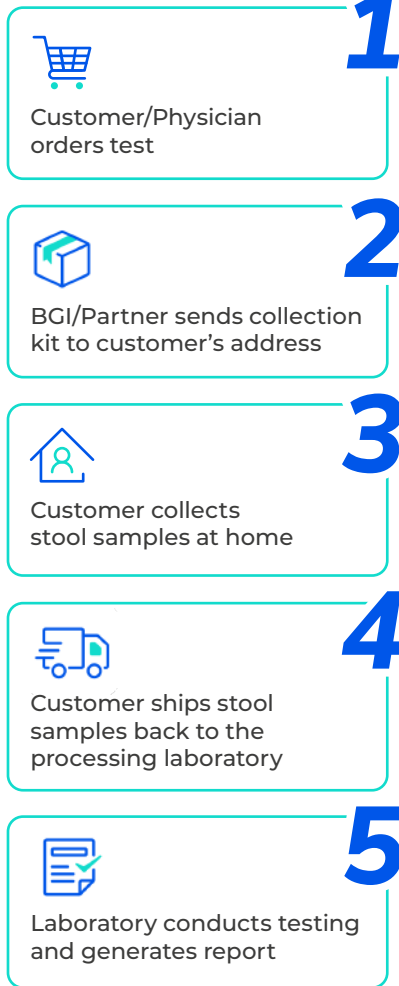


COLOTECT™ 3.0 is a combined human gene methylation and fecal occult blood non-invasive in vitro diagnostic (IVD) assay for qualitative detection of certain genes' methylation and fecal hemoglobin from human stool samples

\* Advanced precancerous lesions including advanced adenoma (tubular adenoma measuring  $\geq 1$  cm in greatest diameter, or adenoma with significant villous features), large serrated lesions or high-grade dysplasia.

# COLOTECT™ 3.0 Testing System Total Solution

## COLOTECT™ 3.0 Testing Journey



## COLOTECT™ 3.0 Testing System Components



Stool Sample Collection Kit (CE marked)



Stool DNA Isolation Kit (CE marked)



Sample Pretreatment Kit for Methylation Detection (CE marked)



Combined Detection Kit for Human Genes Methylation and Fecal Occult Blood (CE marked)

## Testing Instruments



**MGISTP-7000**  
Sample Pre-treatment: 92samples/25min  
\* Hands-on time not included



**MGISP-NE384\***  
Sample Isolation: 92\*4 samples/50min  
DNA Bisulfite Conversion: 92\*4 samples/70min  
\* Hands-on time not included



**qPCR\***  
PCR Analysis: 92 samples/2h  
\*COLOTECT will be compatible with a few PCR platforms



**Reporting Software**  
Report Generation: 10000 samples/2s

## Product Advantages

- Sample collection process is designed with privacy and convenience in mind. Customers can collect stool samples in the comfort of their homes and mail samples back to the processing laboratories.
- Non-invasive and painless test uses stool samples to perform early detection of colorectal cancer and does not require bowel preparation.
- The multi-biomarker DNA and FIT combined testing technology increases rate of detection of colorectal cancer and pre-cancerous lesions, offering ideal performance for colorectal cancer early screening.
- BGI can provide entire end-to-end COLOTECT™ 3.0 testing infrastructure.

## Turnaround time

- 5~10 calendar days (from sample arriving at BGI lab to reporting)

## Testing Reagents

- Stool Sample Collection Kit
- Stool DNA Isolation Kit
- Sample Pretreatment Kit for Methylation Detection
- Combined Detection Kit for Human Genes Methylation and Fecal Occult Blood

## Sample Requirements

- Sample Type: Stool
- Sample Collection: Collect the sample and return the sample within 24 hours after collection
- Sample Storage: Samples can be kept for a maximum of 4 days at room temperature after sample collection. Stool samples for methylation detection can be stored at temperature lower than -20°C for up to 12 months. Stool samples for hemoglobin detection can be stored at temperature lower than -20°C for up to 42 days.

Intended Use and Indications for Use:

COLOTECT™ 3.0 is a noninvasive in vitro diagnostic (IVD) assay for qualitative detection of genes methylation and fecal hemoglobin from human stool sample. The kit is applicable to all people aged 40-75 who need colorectal cancer screening. A positive test result indicates that the subject may have colorectal cancer and/or advanced precancerous lesions (APL), and further colonoscopy is required. This assay is not a replacement for colonoscopy, and the test results of this kit should not be used as the only basis for clinical diagnosis. Clinicians should comprehensively judge the results based on the patient's condition and other laboratory indicators.