COLOTECT™
Non-Invasive Test
for Colorectal Cancer

QR Code Area

COLOTECT Testing
Test Request Form

Testee's Details

Testee's Surname:

Given Names:

Date of Birth: D D M M Y Y Y Y

Gender: Male ☐ Female ☐

Phone Number:

Email:

Address:

Region: City:

Country:

Testee Informed Consent Statement

☒ *I consent to the test of SENTIS COLOTECT™, a non-invasive, highly sensitive test for colorectal cancer (CRC) and precancerous lesions. I confirm that I have acknowledged, understood, and agree to the Informed Consent provided on the **BACK PAGE** of this form.

☒ *I consent to the processing of my personal data by means and for purposes defined in the Privacy Policy.

☒ *I confirm the personal information I have provided is true and correct.

☒ *I consent to the transfer, processing and storage of my sample, information and genetic data abroad, which will comply with applicable laws and policy.

☐ I consent to the preservation and use of my leftover specimens and de-identified test results in the statistics database for research purpose as stated in the Informed Consent. *(Optional)*

Testee Signature:
or **Testee Guardian Signature**

Date: D D M M Y Y Y Y

If you agree, please mark the cross in the box ☒

*In accordance with the applicable regulations, we are not permitted to conduct your tests without these consents.

Collection Information

Sample Type: Stool

Collect Data*: D D M M Y Y Y Y

Resampling*: Yes ☐ No ☐

FOBT test:

No ☐ Negative ☐ Positive ☐

*In accordance with the applicable regulations, we are not permitted to conduct your tests without filling in the data.

Ordering Healthcare Provider's Details

(Optional, if recommended by Doctor)

Doctor's Name:

Service Provider Name: Zentya, a.s.

Address: Grösslingova 4
811 09 Bratislava
Slovensko

Phone Number: +421 915 842 336

Email: colotect@zentya.sk

Testee's Details

(Optional, if recommended by Doctor)

Subject*: Phenotype normal ☐

Patient ☐

Suspected ☐

*Phenotype normal: no related symptoms, Patient: diagnosed with CRC, Suspected: related symptoms, but no diagnosed.

How To Take and Deliver the Sample

1. Fill out and sign this Test Request Form in local and English language version and read the Informed Consent Form on the BACK PAGE of this form.
2. Stick two QR codes on the Test Request Form in local and English language version (QR Code area - at the top right).
3. Third QR code stick on the Sample Return Envelope.
4. Before self-sampling read and then follow the Self-sampling Collection Guide to collect stool samples.
5. Do not forget to write your name and collection date on the Tube.
6. Place the collection tube with a stool sample into the Biohazard Bag, seal this Bag and put it into the Sample Return Envelope.
7. Place the filled and signed Request and Consent Form in English language version into the Sample Return Envelope with a label UN3373. Put the envelope back into the Sample Collection kit (paper box).
8. Send the scan/photo of version in the local language to colotect@zentya.sk on the day of sending the sample (Zentya has to inform the laboratory about sample sending).
9. Prepare 2 sheets of WAYBILL and hand them to the DHL courier together with the sealed Sample Collection kit (Do not put waybills into the Sample Collection kit).
10. Call the courier according to the Instructions for sending the sample.
11. Send the sample and make sure your stool sample is sent within 24 hours after collection.
12. Store the sample at room temperature.

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COLOTECT™
Non-Invasive Test
for Colorectal Cancer

COLOTECT Testing
Informed Consent

PURPOSE

BGI SENTIS COLOTECTTM colorectal cancer test is a non-invasive, highly sensitive test for colorectal cancer and precancerous lesions. Human DNA is extracted from stool sample self-collected at home and used for the multiplex methylation specific PCR. The sensitivity of detecting colorectal cancer is up to 88%, the sensitivity of detecting advanced adenoma is 46%, and the specificity is up to 92%.

TEST PROCEDURE

With the subjects' consents, stool samples collected as instructed will be sent to the BGI laboratory where the DNA in the samples will be isolated and pre-treated with bisulfate for conversion followed by methylation testing to analyse epigenomic alterations associated with colorectal cancer. BGI will then send a detailed report to your service provider/physician, who will deliver the result to you. This information will help you and your physician determine follow-up management and prevention strategies.

RISK NOTIFICATION

The collection of samples for this test will be carried out by the subject himself/herself, and the potential damage arising therefrom is not covered by this informed consent notice.

- If the specimen received does not meet the testing requirements, the subject must actively cooperate with resampling, otherwise, the test results will not be obtained and no refund. The testing cycle must be extended from the date of re-sampling.
- Subjects may have a certain psychological stress burden after knowing the test results, physicians and other professionals will provide counseling and explanation according to the situation.
- Genetic information belongs to the privacy information of the subject and his family. The testing organization will strictly follow the requirements of the regulations and exercise due diligence to protect the privacy and data security of the subject and try to avoid the possibility of privacy leakage due to unavoidable factors.

TEST LIMITATION

- Due to heterogeneity of the sample and other uncontrollable technical reasons, the subject should understand that the test may give false-positive or false-negative results.
- This test provides a choice of auxiliary diagnosis methods for colorectal cancer. Few patients with adenoma or colorectal cancer may result in negative outcomes due to tumor heterogeneity and technical sensitivity, which cannot be detected by this test.
- The personal information provided by the subject must be true and valid. The subject should be responsible for any interruptions in testing and inaccurate test results caused by incorrect, untruth and invalid information.
- As new research outcomes continue to emerge, the subject understands and agrees that this test is provided in accordance with the current status of existing technology and conditions that can achieve the test data. The testing organization will do its best to ensure the effectiveness and safety of the service.

RESULTS

- The results of the test will be reported to the testee by the physician/service provider.
- The results of this test are described objectively, and the results are only responsible for the samples sent for this test.
- This test kit is intended to use for auxiliary diagnosis of patients whose clinicians recommended colonoscopy. The results are only for clinical reference and cannot be used as a criterion for disease diagnosis. A positive test result indicates that the subject may have colorectal cancer and/or advanced adenoma, and further colonoscopy is required; on the contrary, a negative test result indicates that the subject has a low possibility of colorectal cancer and/or advance adenoma, however, the risk of disease cannot be completely ruled out.
- Occasionally samples fail quality control and/or the initial analysis cannot reach a conclusion. This may require resampling and/or reanalysis, which will be offered free but may delay your report. You will be notified by your healthcare provider if this happens.

INTERNATIONAL DATA TRANSFER

The sample and filled information (including first name, last name, address, date of birth and other contact information) will be sent to BGI and/or its partnered laboratories in Europe for testing. We have taken legally required appropriate safeguards to ensure the data protection when transferring your personal data abroad. In principle, samples, information and data of the patient in the European Union, where GDPR provisions apply, will only be processed within the EU. In some situations, your samples, information and data may need to be transferred abroad. This transfer will only take place with your consent.

PRIVACY POLICY

The information and test results of the patient are kept confidential, and all data will remain anonymous during analysis. Only your service provider/physician will receive your test results unless required or authorised by applicable law.

For your test, we need your personal information about your age, sampling collection time. Auditing, quality assurance, and research may use your information. Please read the BGI Privacy Policy (website: **https://www.bgi.com/global/resources/privacy-policy)**, which is in every case considered as part of this consent.

USE OF LEFTOVER SPECIMENS AND INFORMATION

In compliance with better practices, your de-identified specimens and genetic and other information obtained from your tests may be utilised for scientific purposes, technological development, and/or clinical research. Personal information will be removed before reports and publications. All written uses will comply with applicable laws. If you do not agree, your leftover samples will be destroyed after expiry in accordance with international clinical laboratory standards.

The specimens and data will be destroyed if you revoke the test (de- identified data cannot be removed or traced). If you have any questions about your rights as a research subject or concerns, requests or complaints regarding this research, please contact: **info@bgi.com**

RIGHT OF REVOCATION

You may revoke your consent to the test in full or in part at any time, without providing a reason. You have the right not to be informed of test results (right not to know), to halt testing processes at any time prior to receiving the results, and to request the destruction of all test materials and results collected up until that point. However, if the sample has already been processed in the laboratory, the patient cannot request a refund for the test.

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