Informed Consent for Genetic Testing

This form must be completely filled out and signed by you, your parent/legal guardian, or your legally authorized representative. Please read carefully and discuss with your ordering physician/healthcare provider/person obtaining consent before signing.

Purpose
The BGI Sentis ColoTect CRC Screening Test is a non-invasive, highly sensitive screening 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. A sensitivity rate of >87% and a specificity rate of >93% ensures high accuracy and robustness of this test by comparing it with the Gold Standard method, such as colonoscopy.

Procedure
Stool samples collected as the instruction will be sent to a BGI laboratory where the DNA from the sample is isolated and analyzed for cancer-related epigenomic alterations. BGI will then send a detailed report to your healthcare provider who will evaluate your personal health information. This information will help you and your doctor determine subsequent management and preventive strategies.

Testing 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 is for screening purposes. 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

Risk Notification
The collection of samples for this test will be carried out by the medical institution in accordance with clinical treatment standards or 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 hospital and 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 Result and Report
Subjects will be informed of the test report either by obtaining it themselves or by having it forwarded to them by their physician.
The results of this test are described objectively, and the results are only responsible for the samples sent for this test.
This test is a screening technique and cannot be used as a basis for diagnosis. Positive test results do not represent the final diagnosis, and it is recommended that subjects with positive results undergo colorectal microscopy at a hospital in their place of residence to rule out intestinal lesions or have a professional doctor issue a further clinical diagnosis plan.

Accidental discovery (not involved)

Other
Since the occurrence and progression of the disease is a dynamic result, testing after a certain interval of sample collection (more than 3 months) does not represent the real situation of the subject at the moment.

Physician's signature of content:

I certify that the client specified above and/or his/her legal guardian has been informed of the benefits, risks, and limitations of the laboratory test(s) requested. I have answered this person's questions to the best of my ability. I have obtained informed consent from the patient or his/her legal guardian for this test.

Physician´s Printed Name: .....

Date (dd/mm/yyyy): ..... Signature: .....

Declaration of Consent:

I hereby certify that my physician or the person ordering this test has explained the intended purpose, benefits and risks of SentisTM testing referred to in the consent form.

☒ Yes ☐ No

I understand that BGI Clinical Laboratories is only responsible for the genetic test report. This test is not intended to provide a final diagnosis and should, in case of a positive result, not be relied on as sole evidence for a diagnostic conclusion or final clinical decision

☒ Yes ☐ No

I understand that re-sampling may be required if the sample failed to meet the quality criteria for analysis. In case resampling is required, no additional charge will be incurred. I consent to have my test results sent to my healthcare provider, or to an address provided by them.

☒ Yes ☐ No

I understand the analysis is limited to variations on the genes available on the chosen testing option. I understand that due to technical limitations, sample conditions and individual differences, false positive and false negative result can occur.

☒ Yes ☐ No

I understand that my sample or data may be operated and analyzed at a BGI laboratory located in Denmark.

☒ Yes ☐ No

With my signature, I give my consent for genetic analysis and the necessary sampling. It has been pointed out to me that I can withdraw my consent in full or in part at any time without stating reasons, without any resulting detriment and that I have the right to not learn about the test results (right not to know).

I hereby confi¬rm that I have carefully read the BGI PRIVACY POLICY (available on the website https://www.bgi.com/global/resources/privacy-policy/), considered as part of this consent, and that I am fully aware of my rights under this policy. I understand that my personal data will be processed by BGI in order to perform the test as described and in order for BGI to respect its contractual obligations and/or to insure my vital interests or the interests of those of the person of whom I am the legal guardian.

I am aware that I can stop the test once started at any time and can request the destruction of the non-anonymous test material including all components obtained and all result conclusions collected up to that time. However, if the sample has already been processed in the laboratory, I cannot request a refund for the test.

Print Name of Testee/Guardian: .....

Signature of Testee/Guardian: .....

Date (dd/mm/yyyy): .....

If filled by guardian, relationship of guardian to Testee: .....