natera™ | Signatera™
Residual disease test (MRD)

123456-2-X

Please place collection kit barcode here.

PATIENT INFORMATION

Patient Last Name

Patient First Name

Date of Birth (DD/MM/YY)

☐ F ☐ M
Biological Sex

Patient Email

Address

City

Country

Telephone

ORDERING CLINICIAN

Bumrungrad Hospital PCL
Clinic or Organization

Ordering Clinician

12807
Natera® LIMS ID

+6620114160
Telephone

Fax

Bumrungrad Hospital, 33 Sukhumvit 3, Bangkok 10110
Address

LabDepartment@bumrungrad.com
Email

Bangkok
City

Thailand
Country

☐ I hereby authorize the pathology laboratory listed below to release the patient's FFPE tissue to Natera.

SIGNATERA™ TEST ORDERING - MUST CHECK ONE

☐ **SIGNATERA INITIAL TEST** **Sample Requirements: FFPE Tissue:** Requires 6-10, 10-micron slides (or comparable amount of tissue) OR a tissue block. BOTH require a contiguous H&E slide.
Blood Sample: Two 10mL Streck tubes, PLUS one 6mL EDTA tube

Initital Date of Blood Collection (DD/MM/YY)

☐ **SUBSEQUENT TEST** **Sample Requirements: Blood Sample:** Two 10mL Streck tubes

Subsequent Date of Blood Collection (DD/MM/YY)

PATIENT HISTORY (PROVIDE MOST RECENT PROGRESS REPORT)

Cancer Type/Subtype: ☐ Local or Regional CRC ☐ Breast ☐ Lung ☐ Bladder ☐ Other

Subtype

Date of Diagnosis (DD/MM/YY)

Date of Surgery (DD/MM/YY)

ECOG Rating (1-4)

Recent Imaging: Date and Key Findings (e.g. CR, PR, SD, NR)

Stage: ☐ I ☐ II ☐ III ☐ IV ☐ Recurrent ☐ Metastatic

☐ Most recent clinical note attached

*Please note Signatera can only be performed on solid tumor cancers at this time.

PATHOLOGY (SKIP IF SUBSEQUENT TEST)

☐ Pathologist is ordering physician

Pathology report attached: ☐ Yes ☐ No

Pathologist Name

Institution Name

Address

City

Country

Telephone

Fax

Email

Tissue Collection Date (DD/MM/YY)

Block Identifier (e.g. "Block A-left")

Slide Thickness

Surgical ID Number

DISPOSITION OR RETENTION OF SAMPLES

Laboratory (Reseller) represents and confirms that the patient has given informed consent in compliance with applicable law to Natera's following sample disposition or retention policy: PATIENT UNDERSTANDS AND CONSENTS THAT: (i) her/his sample will be sent to the United States for performance of the test; (ii) Natera may retain the patient's leftover, de-identified samples to use for medical and technology advancement, research & development, product validation and quality assurance, independently or in collaboration with third-party partners, either in or outside the United States; and (iii) patient and patient's heirs will not receive any payments, benefits, or rights to any resulting products or discoveries.

Natera, Inc. | 201 Industrial Road, Suite 410 | San Carlos, CA 94070 | www.natera.com | 1-650-249-9090 | Fax 1-650-730-2272 NAT-801982

Barcode Sticker here

Patient Identifier Sticker here

Signatera – Progress Notes:

Cancer type and subtype	
Stage	
Year of diagnosis	
Procedures and date (e.g. biopsy - 12/1/2019, resection - 12/4/2019, etc)	
Treatment history (e.g. neoadjuvant chemotherapy, adjuvant chemotherapy, immunotherapy)	
Most recent imaging and findings (e.g. CT - 12/1/2019 - no evidence of disease)	
Current disease status (e.g. new diagnosis, no evidence of disease, relapse, metastatic)	
Is the patient currently receiving treatment? If yes, please specify. (e.g. Cycle 3 of 12, FOLFOX given 12/1/2019)	
Planned next steps (e.g. surveillance, continued active treatment, etc)	

Signatera International Consent

SIGNED CONSENTS SHOULD BE KEPT IN THE PATIENT MEDICAL RECORD (do not return with the blood kit)

Purpose

Signatera is a personalized molecular test for the detection of circulating tumor DNA (ctDNA) in the blood of patients previously diagnosed with cancer. This testing can be used to detect minimal or molecular residual disease (MRD) following surgery, to monitor response to cancer treatment, or detect cancer recurrence following a period of remission. Each patient will receive a Signatera report showing whether ctDNA was found in the blood (positive result) or not found (negative result). For those with a positive result, the report will also show the quantity of tumor DNA in the blood.

Process

Signatera testing is personalized to each individual's tumor. A sample of your tumor along with a blood sample will be sent to Natera. Using these samples, Natera will identify the unique DNA changes that are found only in the cancer cells of your tumor. Once these unique tumor DNA changes are identified, Natera will develop a customized test which allows us to look for the tumor DNA in future blood tests sent to Natera. Based on these results and other available information, such as your medical history or other test results, your doctor can determine the course of action that is right for you.

Potential Benefits, Limitations, and Risks

These results should be interpreted by your doctor only. Signatera is not a diagnostic test. Signatera can be used to see if ctDNA can be found in your blood at different times, such as after surgery, therapy, or a period of remission. It may also be used during a course of treatment to see whether or not your cancer is responding.

Doctors may have different professional opinions about what Signatera test results mean and whether changes to your treatment plan should occur based upon these test results. Your doctor may recommend continued monitoring with Signatera, lab tests, clinical exams, or imaging studies. Your doctor may choose to continue your current treatment or begin new a therapy to treat your cancer. Other forms of monitoring for response to cancer treatment or recurrence are available and can be used instead of, or alongside, Signatera.

Signatera is a screening test which looks to see if ctDNA is detectable in the blood. If no ctDNA is found, this does not rule out the presence of cancer as some tumors may not be shedding DNA at a level that Signatera can detect. A positive result shows that ctDNA was found at the time the blood sample was taken. Receiving a positive result may cause distress at times, such as the detection of ctDNA in your blood after a period of remission or curative treatment. The meaning of such results can only be interpreted by your doctor, together with the other information that they have about your medical conditions and treatment plan. If ctDNA is found during treatment, it does not necessarily mean that your tumor is not responding to the treatment.

This test is not designed to detect whether you have inherited an increased of developing cancer. Signatera will not determine the cause of your cancer and will not identify possible treatments for your cancer. It is possible that the results of this test could impact your ability to obtain life, disability or long-term care insurance.

Consent for Retaining Samples

Natera is committed to the continual monitoring and improvement of our testing platforms; we may retain your remaining de-identified sample for this purpose. Although future research using de-identified samples may lead to development of new products, it will be impossible to know if your sample was used because samples are stripped of all identifiers. You and your heirs will not receive any payments or benefits from or rights to new products or discoveries. If you DO NOT want any remaining sample to be retained and used for these purposes, you may send a signed request in writing to Natera at: 201 Industrial Rd., Ste 410, San Carlos, CA 94070, Attn: Sample Retention within 60 days after carrier results have been issued, in which case your sample will be destroyed. This will not in any way affect the use of Signatera for monitoring of your cancer.

PATIENT CONSENT STATEMENT:

I have read or have had read to me the above informed consent information about the Signatera test. I confirm that my doctor and/or ordering provider has explained the purpose, benefits, limitations, and risks of Signatera testing. I have had the opportunity to ask questions of my doctor regarding this test, including the reliability of test results, the risks, and the alternatives prior to my informed consent. I request and authorize Natera to test my sample(s) with Signatera and understand that I must also sign this consent form, which will remain in my clinic chart.

Signature of Patient	Date
Printed Name	
Signature of Parent/Guardian	Date
Printed Name of Parent/Guardian	Relationship to Patient