

*Please select your finance billing type:

<input type="checkbox"/> New Guardant Patient	For Existing Guardant Patient, please check:	<input type="checkbox"/> Re-Test due to previous No Mutation Detected (NMD) Reporting (either Liquid/Tissue) (*Only eligible within 8 weeks after the NMD reporting)	<input type="checkbox"/> Bundle Test (Liquid + Tissue)
		<input type="checkbox"/> Previous user of Tissue / Liquid	



clientservicesamea@guardanthealth.com | +65.8940.0360
CLIA # 05D2070300 | CAP Accredited # 8765297 | FRM-PRT-000080 R4

Place
Barcode
Here

Guardant360 Tissue™ Test Requisition

All shaded boxes are REQUIRED to be completed

<h3>1. PATIENT INFORMATION</h3> <p>Last Name _____ First Name _____</p> <p>DOB (dd/mmm/yyyy) _____ Sex <input type="checkbox"/> F <input type="checkbox"/> M Medical Record Number _____</p> <p>Street Address _____</p> <p>City _____ State _____ Country _____ Postal Code _____</p> <p>Preferred Contact Phone Number _____</p> <p><input type="checkbox"/> New Guardant Health Patient <input type="checkbox"/> Existing Guardant Health Patient</p>	<h3>3. ORDERING PHYSICIAN (or other Licensed Medical Professional)</h3> <p>Last Name _____ First Name _____</p> <p>Hospital / Institution _____</p> <p>Email _____</p> <p>Account Name Codex Genetics Limited Account Number GHI-029316</p> <p>Account Address 220 2/F Building 16W</p> <p>City _____ State / Province _____</p> <p>Sha Tin</p> <p>Postal Code 0 Country HK</p> <p>Phone Number +852 30082560 Fax _____</p>												
<h3>2. ADVANCED CANCER STAGE (REQUIRED)</h3> <p><input type="checkbox"/> Advanced Cancer (Stage III/IV)</p>	<p>Medical Professional Consent</p> <p>My signature certifies that: (1) the patient has received an explanation of the purpose, risks, and benefits of the ordered Test(s); (2) the ordered Test(s) are medically necessary and will inform the patient's treatment plan; and (3) the patient, by signing this form, has provided informed consent that meets requirements of applicable law for Guardant Health, Inc.(GH) (continued on back)</p> <p>Medical Professional Signature _____ Date _____</p> <p>X _____</p>												
<h3>4. TEST SELECTION (MUST choose one)</h3> <p><input type="checkbox"/> Guardant360 Tissue + Tissue RNA Select IHC test(s) to add: (At Additional Cost)</p> <p><input type="checkbox"/> Guardant360 Tissue + Tissue RNA + PD-L1 <input type="checkbox"/> ER/PR <input type="checkbox"/> HER2 <input type="checkbox"/> FOLR1</p> <p><input type="checkbox"/> CLDN18 <input type="checkbox"/> c-Met <input type="checkbox"/> Ki-67</p> <p><small>Guardant360 Tissue is a comprehensive next-generation sequencing panel that interrogates 740+ genes and RNA fusions in 360+ genes, includes TMB, MSI status, and promoter methylation data (with/without additional IHC test(s)).</small></p>													
<h3>5. SPECIMEN DETAILS (REQUIRED to complete details and attach patient's pathology report)</h3> <p>Please ensure that FFPE block(s) or unstained slides are provided as per specimen requirements. Pathology Lab Name Codex Genetics Limited</p> <p>Specimen ID _____ Organ Site of Tissue Collection _____ Date of Tissue Collection (dd/mmm/yyyy) _____ Comments _____</p>													
<h3>6. DIAGNOSIS (REQUIRED to select one)</h3> <p>Date of original diagnosis (dd/mmm/yyyy) _____</p> <table border="0"> <tr> <td>BRAIN <input type="checkbox"/> Glioblastoma</td> <td>GI <input type="checkbox"/> Cholangiocarcinoma <input type="checkbox"/> Colorectal Adenocarcinoma <input type="checkbox"/> Esophageal/Gastroesophageal Junction Adenocarcinoma <input type="checkbox"/> Gastric Adenocarcinoma <input type="checkbox"/> Hepatocellular Carcinoma <input type="checkbox"/> Pancreatic Ductal Adenocarcinoma</td> <td>HEAD & NECK <input type="checkbox"/> Head and Neck Carcinoma</td> <td>SKIN <input type="checkbox"/> Melanoma</td> </tr> <tr> <td>BREAST <input type="checkbox"/> Breast Carcinoma</td> <td>GENITOURINARY <input type="checkbox"/> Bladder Carcinoma <input type="checkbox"/> Prostate Adenocarcinoma <input type="checkbox"/> Renal Cell Carcinoma <input type="checkbox"/> Urothelial Carcinoma</td> <td>LUNG <input type="checkbox"/> Adenocarcinoma (NSCLC) <input type="checkbox"/> Large Cell Carcinoma (NSCLC) <input type="checkbox"/> Squamous Cell Carcinoma (NSCLC) <input type="checkbox"/> Small Cell Lung Carcinoma</td> <td>THYROID <input type="checkbox"/> Thyroid Carcinoma</td> </tr> <tr> <td></td> <td>GYNECOLOGIC <input type="checkbox"/> Endometrial Carcinoma <input type="checkbox"/> Ovarian Carcinoma Other <input type="checkbox"/> Gynecologic Tumor</td> <td>SARCOMA <input type="checkbox"/> Sarcoma</td> <td>OTHER <input type="checkbox"/> Other</td> </tr> </table>		BRAIN <input type="checkbox"/> Glioblastoma	GI <input type="checkbox"/> Cholangiocarcinoma <input type="checkbox"/> Colorectal Adenocarcinoma <input type="checkbox"/> Esophageal/Gastroesophageal Junction Adenocarcinoma <input type="checkbox"/> Gastric Adenocarcinoma <input type="checkbox"/> Hepatocellular Carcinoma <input type="checkbox"/> Pancreatic Ductal Adenocarcinoma	HEAD & NECK <input type="checkbox"/> Head and Neck Carcinoma	SKIN <input type="checkbox"/> Melanoma	BREAST <input type="checkbox"/> Breast Carcinoma	GENITOURINARY <input type="checkbox"/> Bladder Carcinoma <input type="checkbox"/> Prostate Adenocarcinoma <input type="checkbox"/> Renal Cell Carcinoma <input type="checkbox"/> Urothelial Carcinoma	LUNG <input type="checkbox"/> Adenocarcinoma (NSCLC) <input type="checkbox"/> Large Cell Carcinoma (NSCLC) <input type="checkbox"/> Squamous Cell Carcinoma (NSCLC) <input type="checkbox"/> Small Cell Lung Carcinoma	THYROID <input type="checkbox"/> Thyroid Carcinoma		GYNECOLOGIC <input type="checkbox"/> Endometrial Carcinoma <input type="checkbox"/> Ovarian Carcinoma Other <input type="checkbox"/> Gynecologic Tumor	SARCOMA <input type="checkbox"/> Sarcoma	OTHER <input type="checkbox"/> Other
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<h3>7. RELEVANT CLINICAL HISTORY</h3> <p>1. The patient is seeking treatment and: <input type="checkbox"/> is newly diagnosed (Stage III/IV). <input type="checkbox"/> has tumor that is not responding to therapy.</p> <p>2. Currently on Therapy? If yes, please list below Date of Therapy Initiation (dd/mmm/yyyy) _____</p> <p><input type="checkbox"/> Targeted Therapy <input type="checkbox"/> Immunotherapy <input type="checkbox"/> Chemotherapy <input type="checkbox"/> Combination Therapy Specific Therapy _____</p> <p>3. Has tissue- or liquid-based CGP from a recent biopsy already returned an actionable result? <input type="checkbox"/> No <input type="checkbox"/> Yes If positive, list mutation: _____</p>													
<h3>8. BILLING INFORMATION</h3> <p><input type="checkbox"/> Hospital/Institution <input type="checkbox"/> Distributor Project Code _____</p>													

GENERAL COMMENTS:



FRM-PRT-000080 R4



Test Requisition & Statement of Medical Necessity *continued*

3. Medical Professional Consent *(continued from front)*

or its reference lab to: (a) collect and use the patient's samples (including genetic material) and health information and perform the ordered Test(s); (b) retain and use samples and health information in accordance with applicable law; and (c) de-identify such samples and information and use and share the resulting de-identified samples and information in accordance with applicable law. My signature constitutes a Certification of Medical Necessity, and I hereby authorize and order GH to perform testing and curation for this patient as indicated on this requisition. If no Test is selected, this indicates an order for Guardant360 Tissue+ Tissue RNA. I have reviewed the medical consent on this form and will provide Test interpretation to the patient as appropriate. As may be required by applicable laws and regulations, I have informed the patient regarding somatic genomic testing and immunohistochemistry (IHC) testing (if selected), and the patient has consented for the tests ordered. The patient understands that his/her anonymized results may be used by GH for the purpose of laboratory test improvement and publication of aggregated data. I understand that GH is relying on the diagnosis I have provided on the test requisition form in providing information about potential therapeutic options and clinical trials associated with the reported testing results, and that an incorrect diagnosis would adversely affect the relevance of the information provided by GH. I understand that I remain free in my medical decisions on how to use the results of any GH product(s) in my management of this patient. I have obtained the patient's written consent to transmit the health data on this requisition form for the purpose of processing this order and performing all ordered GH tests. Where applicable, I authorize GH to release the report to the patient directly. By submitting this request, I acknowledge that personal data will be processed in accordance with to GH's privacy policy (www.GuardantHealth.com/contact/privacy-policy).

FFPE Block Return Information (For AMEA CS USE ONLY)

FFPE Block Return Address _____

City _____ State _____ Postal Code _____ Country _____

Phone _____ Email _____

Patient Consent

Your healthcare provider has ordered certain tests offered by Guardant Health, Inc. (GH)(the "Tests").

The Tests may detect both somatic (not inherited) and germline (inherited) alterations; however, the Tests do not distinguish between such mutations. Therefore, the Tests do not provide information about propensity to develop disease in the future. However, if a reported alteration is suspected to be germline, confirmatory hereditary testing should be considered in the appropriate clinical context. These Tests are not intended to replace germline testing or to provide information about cancer predisposition. Your healthcare provider will consider whether follow up confirmatory germline testing is appropriate for you. You may wish to discuss with your healthcare provider about seeking genetic counseling from a genetic counselor before undergoing germline testing.

By signing below, you consent to undergo the Test and you acknowledge and/or agree that:

- You have been informed by your physician about the purpose, scope, and limitations of the test ordered. The Test reports do not provide a definitive medical diagnosis or make any specific treatment recommendations; instead they provide information for your healthcare provider to review. GH does not guarantee that a Test will yield clinically relevant information, inform your healthcare provider's clinical decision-making, or otherwise lead to any particular or beneficial outcome. Some Test results may show one or more "actionable" genomic alterations, meaning that there may be: (i) FDA-approved therapies available that target a specific disease subtype; (ii) certain clinical trials available to you; or (iii) genetic information that may impact your ongoing healthcare management. The Tests do not examine every possible genetic variant and may not identify all variants related to you or your disease, because: (i) there is a possibility of testing errors; (ii) biological factors may limit the accuracy of results; or (iii) the presence of a mutation may be below the limit of detection for the Tests. GH is not obligated to update, revisit, or later re-evaluate Test results after they have been sent to your healthcare provider.
- You authorize release of pathology tissue samples, blood, and/or other materials, including extracted DNA and RNA, requested by GH ("Materials") to conduct the Tests, and direct the applicable pathology lab to release all such Materials to GH. You understand that your Materials will be collected and transported by third party logistics carriers to GH in the US for analysis and interpretation. You acknowledge that the Materials may be lost, delayed or damaged during handling or transit by third party logistics carriers, and assume all associated risks. You hereby release, waive, and discharge GH and its Affiliates from any and all claims, liabilities, or causes of action arising from loss or damage in transit. You further acknowledge that the Materials may be irreplaceable and the maximum liability of GH, if any, shall be limited to the amount paid by you for the Test.
- Your Materials, personal data, and health information will be transferred to GH in the United States, and the data protection laws in the United States may differ from those in your home country in how they safeguard your personal data.
- GH will be processing your personal data (including your Materials and health information). GH collects, uses, discloses, or processes your Personal Data for the following purposes as described in GH's Privacy Policy available at: <https://guardanthealth.com/contact/privacy-policy/>: (i) carrying out the Test; (ii) providing Test-related communications to you or your healthcare provider or institution; (iii) billing-related activities; (iv) managing GH's administrative and business operations; (v) carrying out your instructions; (vi) performing other permitted or reasonably related activities; and (vii) complying with GH's legal obligations and/or a government request. Carrying out the purposes will involve the overseas transfer and storage of your Personal Data, including to GH's facilities in the United States. Furthermore, subject to applicable law, GH may remove certain identifying information from your personal data (such as by de-identifying, pseudonymizing, or anonymizing your personal data) and process such data for its scientific research purposes related to cancer diagnostic product improvement and development, including publication of aggregated data. Certain third parties may process and store your personal data as detailed in GH's Privacy Policy, including third parties appointed by GH and/or its affiliates, necessarily involved in the process of ordering, taking, collecting, delivering, testing your sample and reporting.
- You understand that the results of the Test will be sent or made available to your physician, and when the results are ready, you will collect the Test results from your physician.
- You have read and understand the information set out above in this form, and that you: (i) had the opportunity to ask any questions that you might have regarding the Test and the process related to the Test; and (ii) received satisfactory answers from your physician.
- For patient under 18 years of age, you certify that you are the guardian of the patient and on behalf of the patient, you hereby agree for the patient to undergo the Test and for the patient's personal data to be processed as set out above.
- You authorize the below listed individual to have access to your personal data, including your health information, Test updates, and reports (Optional):

Full Name of Authorized Family Member: _____

Date of Birth (DOB) of Authorized Family Member: _____

Relationship status with the patient: _____

Phone number: _____

Email address: _____

SIGNATURE
DATE

PRINT NAME
EMAIL ID OF PATIENT

NAME OF PATIENT (IF DIFFERENT FROM THE SIGNATORY)

[Fill this form ONLY when tissue specimen retrieval from third-party laboratory is needed]

Date: _____

To: Histopathology Laboratory, _____ (Hospital Name)

RE: Sample Retrieval and Preparation for Cancer Tissue Testing for Patient _____ (Name), HKID: _____

To Whom It May Concern,

Please accept this letter as formal authorization to your laboratory to:

1. **Retrieve** archived tissue specimen(s) of the indicated patient,
2. **Prepare** the specimen(s) based on the specimen requirements of the selected test request, and
3. **Release** the prepared specimen(s) to the **Codex Genetics** in handling all test requisition documents to the third-party service provider and local logistics for sample pick-up and transportation.

NO. OF SLIDES REQUIRED	CORE REQUIREMENT														
<input type="checkbox"/> For Guardant360 TissueNext + PDL1 Dako22C3: 8 FFPE unstained coated slides <hr style="border-top: 1px dashed black;"/> <input type="checkbox"/> Additional Guardant IHC Testing: <i>(*Please check the box for each additional test request)</i> <table border="1" style="margin: 10px auto; border-collapse: collapse; text-align: center;"> <thead> <tr style="background-color: #cccccc;"> <th style="padding: 5px;">Additional Biomarker</th> <th style="padding: 5px;">No. of additional slides required</th> </tr> </thead> <tbody> <tr><td style="padding: 5px;"><input type="checkbox"/> c-MET</td><td style="padding: 5px;">+1</td></tr> <tr><td style="padding: 5px;"><input type="checkbox"/> HER2</td><td style="padding: 5px;">+1</td></tr> <tr><td style="padding: 5px;"><input type="checkbox"/> Ki-67</td><td style="padding: 5px;">+1</td></tr> <tr><td style="padding: 5px;"><input type="checkbox"/> ER/PR</td><td style="padding: 5px;">+2</td></tr> <tr><td style="padding: 5px;"><input type="checkbox"/> FOLR1</td><td style="padding: 5px;">+2</td></tr> <tr><td style="padding: 5px;"><input type="checkbox"/> CLDN18</td><td style="padding: 5px;">+3</td></tr> </tbody> </table>	Additional Biomarker	No. of additional slides required	<input type="checkbox"/> c-MET	+1	<input type="checkbox"/> HER2	+1	<input type="checkbox"/> Ki-67	+1	<input type="checkbox"/> ER/PR	+2	<input type="checkbox"/> FOLR1	+2	<input type="checkbox"/> CLDN18	+3	<p>For all Guardant tests:</p> <ul style="list-style-type: none"> FFPE unstained coated slides, 5µm thick each Surface Area <ul style="list-style-type: none"> Minimum: ≥ 2 mm² Optimum: 25mm² Tumor Content <ul style="list-style-type: none"> Minimum: ≥ 5% Optimum: ≥ 20% <p>Pathology report is required.</p>
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<input type="checkbox"/> CLDN18	+3														
<p>Total No. of Slides Required: _____</p>	<p>For all CONCISE tests:</p> <ul style="list-style-type: none"> 5µm thick each Surface Area ≥ 20 mm² Tumor Content : ≥ 5% <p>Pathology report is required.</p>														
<input type="checkbox"/> For CONCISE LungScan / ColoScan 10 FFPE unstained coated slides	<p>For all CONCISE tests:</p> <ul style="list-style-type: none"> 5µm thick each Surface Area ≥ 20 mm² Tumor Content : ≥ 5% <p>Pathology report is required.</p>														

Bill to: Codex Genetics Limited, Unit 220, 2/F, Hong Kong Science Park 16W, Shatin, N.T.

For any enquiries, please contact Ms. Sherie Lee (Codex Genetics) at 3008 2560 for specimen collection and logistics.

I, Dr. _____ (Dr. Name), hereby to confirm that the indicated patient has understood and accepted the recommendation for the genetic testing service, that this specimen retrieval and preparation is medically indicated. I authorize both your laboratory and Codex Genetics to proceed as outlined.

Yours Sincerely,

Clinician Name:

Patient Name:

Clinician Signature:

Patient Signature: