



LBL-000542 R1

TEST REQUISITION FORM – ESR1 SPONSORED TESTING PROGRAM*

All fields must be completed unless otherwise noted

PATIENT INFORMATION			
Last Name		First Name	
DOB (mm/dd/yyyy)	Sex ☐ F ☐ M	Medical Record Number	
Street Address			
City	State	Country	Zip
Phone		Email (for test status updates)	

DIAGNOSIS	BLOOD COLLECTION
☐ Breast Carcinoma (HR+/HER2-)	(mm/dd/yyyy)

TEST SELECTION



Guardant360 CDx

Select this checkbox to run a Guardant360 CDx test to assess possible *ESR1* mutations in this patient.

Please review the program eligibility criteria in the Terms and Conditions.* After review, confirm the patient's eligibility by checking the box below.

☐ The patient satisfies the eligibility criteria for the program, as listed in the Terms and Conditions.



Medical Professional Consent Signature

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) 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) obtain, receive, and release health information (including Test results) as necessary for performance to the Test; (c) retain and use samples and health information for an indefinite period of time in accordance with applicable law; and (d) 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 and its performing laboratory to perform testing and curation for this patient as indicated on this requisition. If no Test is selected, this indicates an order for Guardant360 CDx. 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 state laws and regulations, I have informed the patient regarding somatic genomic testing, and the patient has consented for the tests ordered. I understand that GH is relying on the diagnosis or diagnosis code 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 or diagnosis code 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. By submitting this request, I acknowledge and agree to the GH privacy policy (www.guardanthealth.com/contact/privacy-policy).

For the complete intended use statement, including companion diagnostic indications, please see the Guardant360 CDx Technical Information: www.guardant360CDx.com/technicalinfo.

*GUARDANT HEALTH ESR1 SPONSORED TESTING PROGRAM – TERMS AND CONDITIONS

The Guardant Health Sponsored Testing Program (the "Program") is offered by AstraZeneca Pharmaceuticals (AstraZeneca) in order to address patient barriers to clinically appropriate, provider prescribed testing. Through the Program, AstraZeneca, through an arrangement with Guardant Health (Guardant), makes the Guardant360 CDx test available at no-charge for certain eligible patients with advanced breast cancer.

Patients must meet all of the following criteria to be eligible for the Program (collectively, the "Eligibility Criteria"):

- The patient has histologically confirmed HR-positive, HER2-negative locally advanced breast cancer and is on first-line endocrine treatment
- The patient is on CDK 4/6 inhibitor and aromatase inhibitor (AI) therapy with no evidence of progression
- Testing of the patient's sample is consistent with the Guardant assay CDx label
- The patient's insurance does not cover repeat NGS testing prior to radiological progression
- This test will be used for *ESR1* monitoring
- The *ESR1* test is clinically appropriate and medically necessary for the patient

The Program covers the cost of one Guardant360 CDx test per eligible patient. To participate in the Program, the provider must sign the order form as an attestation that confirms that: (i) the patient satisfies the Program Eligibility Criteria; (ii) the provider believes that *ESR1* testing via Guardant360 CDx test is clinically appropriate and medically necessary for the patient; (iii) the patient's insurance provider does not cover repeat next-generation sequencing testing; and (iv) the provider has obtained consent necessary to comply with applicable law.

The Program is open to any patient who meets the Eligibility Criteria, regardless of insurance status. There is no obligation to recommend, purchase, order, prescribe, promote, administer, use, or support any AstraZeneca, Guardant, or other third party product or service to participate in the Program.

The Program does not cover any additional services associated with the patient's treatment. No patient, provider, or payer, including government payers, are billed for the Program. Providers may not seek reimbursement from any patient or third party payer (including commercial health plans and government health care programs) for the Guardant360 CDx test or other services provided in connection with the Program.

AstraZeneca does not receive patient- or provider-identifiable information in connection with the Program. AstraZeneca retains the right to amend or rescind the Program at any time. While AstraZeneca provides financial support for the Program, tests and services are performed by Guardant. AstraZeneca assumes no liability and provides no warranties for the testing services provided by Guardant.

The Program is available only in the United States in the 50 states and District of Columbia.

Required to Include:	Recommended to Include:
☒ Facesheet	☒ Clinical Notes



Order on the Guardant Portal

Scan QR code to be directed to the Guardant Portal for a digital ordering experience or visit <https://www.GHSponsoredTesting.com/Ordering>

Place Barcode Here

ORDERING PHYSICIAN (OR LICENSED MEDICAL PROFESSIONAL)

Medical Professional Signature		Date (mm/dd/yyyy)
		
Last Name	First Name	
Email		
GHI #		
Account Name		
Street Address	City	
State	Zip	Fax Number



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Patient Consent

Your healthcare provider has ordered the Guardant360 CDx test offered by Guardant Health (GH) (the “Tests”). 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, saliva, cheek swab samples, 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. For genetic Tests that require Materials, genetic Material including DNA and/or RNA will be obtained, stored, and analyzed by GH and/or a reference lab. You understand that the Materials may be irreplaceable and could be lost or damaged in handling, transit, or when used. The Tests will generate health data about you and GH or the reference lab may receive health data from your medical record in connection with the Tests. Your identifiable data is subject to legal requirements regarding its use and protection. GH may use and disclose the Test results and your other health data as described in its notice of privacy practices (NPP). GH’s current NPP, which includes information about how de-identified DNA analysis and other health data may be commercially used and shared in or out of the United States with life science companies or others, is available at <https://guardanthealth.com/contact/notice-of-privacy-practices-under-hipaa-for-us-residents/>. Unless prohibited under applicable law, leftover Materials may be retained indefinitely and used and shared for quality, test validation, and other purposes described in the NPP. Third parties receiving de-identified data or Materials are prohibited from using it to re-identify you.

The Tests may detect both somatic (not inherited) and germline (inherited) alterations; 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 understand and have discussed with your healthcare provider that because these Tests do not distinguish between germline and somatic mutations, no level of certainty has been established that any possible germline mutations identified in Test results are a predictor of a given disease. 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 acknowledge that: (i) you have read and understand the information provided about the Tests; (ii) you understand that the Tests are voluntary; (iii) you may choose not to have any Test; (iv) you consent to the genetic testing and to the other matters listed, including collection, use, retention, maintenance, and disclosure of your Materials and the results of any DNA analysis; and (v) this consent shall remain valid for any series of Tests ordered by your provider that may be completed within one (1) year of your signature. By providing your contact information and undergoing the Tests, you acknowledge that GH and its representatives may email, call, and / or text you with messages about your healthcare, including reminders about any Tests your provider has ordered, the release of Test results, information about follow-up Tests from GH, payment for Tests, and your experience receiving care from GH, at any phone number you provide, including a wireless number, using prerecorded calls or automated technology. You understand that you may unsubscribe by following the link within emails or opt-out of text messages at any time by replying “STOP.” Standard text message and data rates may apply. If law requires you to consent to these terms, but you have been unable to sign, provision of your Materials to GH indicates your consent. Revisions to this form are void. If you are signing on behalf of the patient, you further certify that you have legal authority to consent on behalf of the patient.

Patient Signature for Consent

X Patient Signature	Print Name of Patient Date (mm/dd/yyyy) Email
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