Guardant360® CDx is a blood test that helps your doctor better understand your cancer

Expect your results in 7 days*
To be notified when your results are ready, visit myGuardant Patient Portal at patients.guardanthealth.com

We will evaluate your insurance coverage
And will make every attempt to contact you if your out-of-pocket responsibility exceeds $100

Questions?
We want to hear from you.
Contact Client Services
855.698.8887
clientservices@guardanthealth.com
www.guardanthealth.com

Inform your treatment plan with a simple blood draw

For Patients

To activate your account, visit patients.guardanthealth.com

*7 days is approximately from when Guardant Health receives the sample to report delivery.
Guardant Access
When you or a loved one is battling cancer, the last thing you want to worry about is an unexpected bill amount or confusing paperwork.

That’s why we created Guardant Access, a program that manages the billing process for you. At no cost to the patient, Guardant Access checks your eligibility, for financial assistance, helps manage claims appeals with insurance companies, and handles your billing questions.

If you enroll in the Guardant Access program in 2020, Guardant Health will confirm your insurance and eligibility for financial assistance and will make every attempt to contact you before your sample is tested if your expected out-of-pocket responsibility exceeds $100.

To enroll in the Guardant Access program, all you need to do is sign the back of the Test Order Form with your doctor. If you are not sure if you signed the form contact Guardant Health Client Services and we will enroll you in the program.

What is Guardant360 CDx?
Guardant360 CDx is an FDA approved liquid biopsy test that provides your doctor with a list of select genomic alterations specific to your cancer, providing them confidence that Guardant360 CDx helps inform a treatment plan for you.

Questions?
We want to hear from you.

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Guardant360 CDx is an FDA approved liquid biopsy test that provides your doctor with a list of select genomic alterations specific to your cancer, providing them confidence that Guardant360 CDx helps inform a treatment plan for you.

Going forward, your care team can have the answers they need to guide your treatment plan.
Guardant360 CDx can help

Genomic testing, the identification of select alterations unique to your cancer, is an important step after a cancer diagnosis. Guardant360 CDx provides genomic testing for advanced cancer patients with results in 7 days. It starts with a routine blood draw that happens in your doctor’s office. The results can help your doctor understand if your tumor has certain alterations and determine the right path for treatment.
Access test results that may inform your treatment plan
For patients with advanced cancer, targeted therapy is a promising treatment option and Guardant360 CDx may help determine the right treatment plan for you.

How it works

- **DAY 0**
  - Blood Drawn
  - Blood sample received at lab

- **DAY 1**
  - Sample Processing Begins
  - Guardant360 reads and interprets the cancer DNA in your blood
  - Guardant360 report released to your doctor
  - You and your doctor review your Guardant360 results

We will verify your insurance eligibility and make every attempt to contact you if your out-of-pocket expense may exceed $100.

*Not every alteration has an associated therapy or clinical trial.*

Seeing the full picture
As a blood test, Guardant360 captures the DNA that is shed from your tumor. This provides a comprehensive overview of your cancer genomics from both your primary tumor and any metastatic sites.

Your report shows your cancer's genomic alterations detected in the blood. Associated FDA-approved therapies and drugs still in clinical trials are listed where available.* Your physician will interpret your results to identify the best treatment option for you.

*Not every alteration has an associated therapy or clinical trial.*
Guardant360® CDx test helps select eligible NSCLC patients for treatment with TAGRISSO® (osimertinib). The test also provides genomic information to your doctor that can help guide your care.

Your doctor may change your treatment based on these results.

Results in 7 days*

To be notified when your results are ready, visit myGuardant Patient Portal at patients.guardanthealth.com

We are available to answer your questions

Call Client Services at 855.698.8887 or email us at clientservices@guardanthealth.com

*7 days is approximately from when Guardant Health receives the sample to report delivery.
How Guardant360 CDx works

1. **Blood Draw**: Day 0
   - We will verify your insurance eligibility and make every attempt to contact you if your expected out-of-pocket responsibility exceeds $100.

2. **Blood Sample Received by Lab**: Day 1
   - We will verify your insurance eligibility and make every attempt to contact you if your expected out-of-pocket responsibility exceeds $100.

3. **Sample Processing Begins**: Day 1
   - Guardant360 CDx reads and interprets the cancer DNA in your blood.

4. **Guardant360 CDx Results**: Day 7
   - You and your doctor review your Guardant360 CDx results.

**Guardant Access** is a program that manages the billing process for you:

- At no cost to you, we will evaluate your insurance coverage and will make every attempt to contact you if your expected out-of-pocket responsibility exceeds $100.
- We will evaluate your eligibility for financial assistance, no matter what type of insurance coverage you have.
- To be eligible for financial assistance, you must sign the Test Order Form.
- In order for you to qualify for financial assistance and for Guardant Health to handle the billing process for you, your signature on the back of the Test Order Form is required. If you are unsure if you signed the Test Order Form, please contact Guardant Health Client Services.

**Information for Medicare Patients:**

- CDx® is FDA approved.
- Guardant360 CDx is covered by Medicare.
Searching for guideline-complete genomic information? Get results faster.

Guide treatment decisions in 7 days

GUARDANT 360 CDx
Guardant360 CDx Intended Use

Guardant360® CDx is a qualitative next generation sequencing-based in vitro diagnostic device that uses targeted high throughput hybridization-based capture technology for detection of single nucleotide variants (SNVs), insertions and deletions (indels) in 55 genes, copy number amplifications (CNAs) in two (2) genes, and fusions in four (4) genes. Guardant360 CDx utilizes circulating cell-free DNA (cfDNA) from plasma of peripheral whole blood collected in Streck Cell-Free DNA Blood Collection Tubes (BCTs). The test is intended to be used as a companion diagnostic to identify non-small cell lung cancer (NSCLC) patients who may benefit from treatment with the targeted therapy listed in Table 1 in accordance with the approved therapeutic product labeling.

Table 1: Companion Diagnostic Indications

<table>
<thead>
<tr>
<th>Indication</th>
<th>Biomarker</th>
<th>Therapy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-small cell lung cancer (NSCLC)</td>
<td>EGFR exon 19 deletions, L858R, and T790M*</td>
<td>TAGRISSO® (osimertinib)</td>
</tr>
</tbody>
</table>

A negative result from a plasma specimen does not assure that the patient’s tumor is negative for genomic findings. NSCLC patients who are negative for the biomarkers listed in Table 1 should be referred to tissue biopsy testing for Table 1 biomarkers using an FDA-approved tumor tissue test, if feasible.

*The efficacy of TAGRISSO® (osimertinib) has not been established in the EGFR T790M plasma-positive, tissue-negative or unknown population and clinical data for T790M plasma-positive patients are limited; therefore, testing using plasma specimens is most appropriate for consideration in patients from whom a tumor biopsy cannot be obtained.

Additionally, the test is intended to provide tumor mutation profiling to be used by qualified health care professionals in accordance with professional guidelines in oncology for cancer patients with any solid malignant neoplasms. The test is for use with patients previously diagnosed with cancer and in conjunction with other laboratory and clinical findings.

Genomic findings other than those listed in Table 1 are not prescriptive or conclusive for labeled use of any specific therapeutic product.

Guardant360 CDx is a single-site assay performed at Guardant Health, Inc.

For additional information, please see the Guardant360 CDx Technical Information document:
www.guardant360cdx.com/technicalinfo

Guardant360® CDx has demonstrated concordance to Guardant360® LDT for the CDx variants

There is established concordance between Guardant360 CDx and the Guardant360 lab-developed test (LDT) for the specific CDx variants (EGFR exon 19 deletion, L858R, and T790M alterations).

Guardant360 CDx is concordant with Guardant360 LDT for the CDx variants

<table>
<thead>
<tr>
<th>Variant Category</th>
<th>Test as Comparator Method</th>
<th>Variant Category</th>
<th>LDT as Comparator Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>EGFR L858R</td>
<td>95.1%</td>
<td>EGFR L858R</td>
<td>98.0%</td>
</tr>
<tr>
<td>EGFR Exon 19 del.</td>
<td>98.8%</td>
<td>EGFR T790M</td>
<td>95.6%</td>
</tr>
<tr>
<td>EGFR T790M</td>
<td>95.8%</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Warnings and Precautions

- Alterations reported may include somatic (not inherited) or germline (inherited) alterations. The assay filters germline variants from reporting except for pathogenic BRCA1, BRCA2, ATM, and CDK12 alterations. However, if a reported alteration is suspected to be germline, confirmatory testing should be considered in the appropriate clinical context.
- The test is not intended to replace germline testing or to provide information about cancer predisposition.
- Somatic alterations in ATM and CDK12 are not reported by the test as they are excluded from the test’s reportable range.
- Genomic findings from cfDNA may originate from circulating tumor DNA (ctDNA) fragments, germline alterations, or non-tumor somatic alterations, such as clonal hematopoiesis of indeterminate potential (CHIP).
- Allow the tube to fill completely until blood stops flowing into the tube. Underfilling of tubes with less than 5 mL of blood (bottom of the label indicates 5 mL fill when tube is held vertically) may lead to incorrect analytical results or poor product performance. This tube has been designed to fill with 10 mL of blood.

Limitations

- For in vitro diagnostic use.
- For prescription use only. This test must be ordered by a qualified medical professional in accordance with clinical laboratory regulations.
- The efficacy of TAGRISSO® (osimertinib) has not been established in the EGFR T790M plasma-positive, tissue-negative or unknown population and clinical data for T790M plasma-positive patients are limited; therefore, testing using plasma specimens is most appropriate for consideration in patients from whom a tumor biopsy cannot be obtained.
- TAGRISSO® efficacy has not been established in patients with EGFR exon 19 deletions < 0.01% MAF, in patients with EGFR L858R <0.01% MAF, and in patients with EGFR T790M < 0.03% MAF.
- The test is not intended to be used for standalone diagnostic purposes.
- The test is intended to be performed on specific serial number-controlled instruments by Guardant Health, Inc.
- A negative result for any given variant does not preclude the presence of this variant in tumor tissue.
- The test is not intended to be used for standalone diagnostic purposes.
- On patient care and treatment must be based on the independent medical judgment of the treating physician, taking into consideration all applicable information concerning the patient's condition, such as patient and family history, physical examinations, information from other diagnostic tests, and patient preferences, in accordance with the standard of care.
- ctDNA shedding rate may be lower in patients with primary central nervous system (CNS) tumors.

For the complete intended use statement, including companion diagnostic indication, please see the Guardant360 CDx Technical Information:
www.guardant360cdx.com/technicalinfo
Today’s first-line treatments for advanced NSCLC are more effective than ever before

Optimal treatment decisions can only be made after complete genotyping

Immunotherapy and targeted therapies improve overall survival, but only for the right patients

- ~21% of advanced NSCLC patients have alterations associated with currently FDA-approved drugs

- ~63% of advanced NSCLC patients have alterations associated with guideline-recommended alterations

First-line Median overall survival in months

- XALKORI® (crizotinib)
- TAGRISSO® (osimertinib)
- KEYTRUDA® (pembrolizumab)
- ALECENSA* (alectinib)
- TAFINLAR® + MEKINIST® (dabrafenib, trametinib)
- KEYTRUDA® + chemo (pembrolizumab) + combination chemotherapy

NCCN guideline-recommended alterations occur in most patients

- First-line treatment is critical because only 1 in 2 patients will make it to 2L therapy

Immunotherapy is inappropriate for patients with targetable alterations

- Minimal response to immune checkpoint inhibitors, even when PD-L1 is ≥50%
- All checkpoint inhibitor labels exclude patients who have EGFR and ALK alterations

Patients with targetable alterations

EGFR+ | ALK or EGFR+ | BRAF V600E+
---|---|---
14%-20% | 4% | 13%

Survival rates

- 60%-70% | 60%-70% | 64%

- EGFR+, ALK or EGFR+, BRAF V600E+

- ORR to targeted therapy | ORR to immunotherapy

- First-line treatment is critical

Getting first-line treatment is critical because only 1 in 2 patients will make it to 2L therapy
Less than 1 in 2 NSCLC patients get complete genotyping from tissue\textsuperscript{17-21}

Standard-of-care tissue testing leaves many patients untested for NCCN guideline-recommended alterations\textsuperscript{22}

<table>
<thead>
<tr>
<th>Gene</th>
<th>% of patients tested with tissue</th>
</tr>
</thead>
<tbody>
<tr>
<td>EGFR</td>
<td>83%</td>
</tr>
<tr>
<td>ALK</td>
<td>80%</td>
</tr>
<tr>
<td>ROS1</td>
<td>58%</td>
</tr>
<tr>
<td>BRAF</td>
<td>35%</td>
</tr>
<tr>
<td>RET</td>
<td>22%</td>
</tr>
<tr>
<td>MET (exon 14 skipping)</td>
<td>23%</td>
</tr>
<tr>
<td>MET (amplification)</td>
<td>22%</td>
</tr>
<tr>
<td>ERBB2</td>
<td>20%</td>
</tr>
<tr>
<td>All 8</td>
<td>18%</td>
</tr>
</tbody>
</table>

Only 31\% of patients were tested by tissue for all 4 alterations associated with FDA-approved therapies

Tissue challenges exist across practice settings

Comprehensive tissue panels require more tissue than may be available\textsuperscript{23}

Only 56\% of patients eligible for tissue biopsy were able to get complete genomic results from tissue testing

- Patients who received complete genomic results from tissue
- Patients who did not receive complete genomic results from tissue
Tissue has challenges beyond your control that prevent complete genotyping

Avoid challenges inherent to tissue testing with Guardant360 CDx

Reasons why tissue fails at complete genotyping

**Finite resource**
Exhausted by histopathology stains and PD-L1 testing

**Practice/staff burden**
Significant coordination involving multiple care team members

**Patient burden**
Repeated tissue biopsies expose patients to potential adverse events

**Lengthy process**
Results can be unpredictable, may take up to a month or longer, and can be incomplete

Complete genotyping with tissue can take many weeks or longer*
A simple blood draw easily implemented into your workflow

Everything you and your patients need to get started

End-to-end support to manage billing
On-call support for MDs and patients
Medicare coverage for advanced solid tumors*

Guardant Access manages the billing process for your patients

**Insurance & Eligibility confirmation**
Insurance eligibility confirmation and patient outreach if patient out-of-pocket cost exceeds $100 for all patients
Assessment of financial assistance eligibility regardless of insurance type

**Easy enrollment**
Any patient can enroll for financial assistance eligibility determination by signing the back of the Test Requisition Form or contacting Guardant Health Client Services

Easy access to reports

Access reports via fax, online portal, or app
Get real-time email and in-app notifications when results are ready

**Your Reports**

Johnson, Robert  
2018-03-12 FINAL  
Lung adenocarcinoma

Doe, John  
2018-01-12 FINAL  
Non-small cell lung carcinoma (NSCLC)

For the complete intended use statement, including companion diagnostic indication, please see the Guardant360 CDx Technical Information: www.guardant360.com/guardant360cdx

*Excluding central nervous system tumors

*From sample receipt to report
Published data on the clinical performance of Guardant360 LDT

Disclaimer: This content has not been reviewed by the FDA. Data shown for the performance of Guardant360 laboratory developed test (LDT) does not convey the performance of Guardant360 CDx.
Guardant360 LDT is supported by peer-reviewed and published clinical data

Guardant360 LDT has demonstrated consistently high concordance to tissue testing

Complete and fast genomic results you can trust

95% of patients\(^2\)

Guideline-recommended testing for NSCLC alterations

1st Liquid biopsy

Covered by Medicare for all patients with advanced cancer across solid tumors* 7 Days

Fast results to guide treatment decisions

Unparalleled clinical validation and utility across multiple studies

150+ Peer-reviewed publications

Including multiple head-to-head, prospective studies

50+ Clinical outcome studies

Response rates to therapy selected based on Guardant360 results are consistent with tissue-based studies

Evidence from multiple prospective clinical studies\(^{22-23}\)

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**Concordance (%)**

Guardant360 to tissue NGS before first-line therapy (n=323) For guideline-recommended alterations

Guardant360 to SOC tissue before first-line therapy (n=282) For EGFR, ALK, BRAF, and ROS1

15%-20% of the time tissue misses what liquid finds and vice versa\(^{25}\)

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% not detected

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Results for single nucleotide variants (SNVs) from 165 patient samples across multiple solid tumors

Clinical specificity of nearly 100% for Guardant360 vs comprehensive tissue testing and vice versa

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% detected

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90% 98%

85% 81%

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Disclaimer: This content has not been reviewed by the FDA. Data shown for the performance of Guardant360 laboratory developed test (LDT) does not convey the performance of Guardant360 CDx.

*Excluding central nervous system tumors
NILE study found Guardant360 LDT enabled increased patient testing, more alterations detected, faster results.

When Guardant360 LDT was used first, more patients were found with targetable alterations.

Key Findings

Study Objectives

Compare Guardant360’s ability to detect guideline-recommended genomic alterations in patients newly diagnosed with advanced NSCLC to standard-of-care (SOC) tissue testing.

Study Design

Head-to-head, prospective, multi-center study of 282 patients newly diagnosed with advanced NSCLC.

Study Results

Guardant360 LDT demonstrated greater than 98% concordance to SOC tissue testing for EGFR, ALK, BRAF, ROS1 tested for guideline-recommended alterations vs tissue testing.

Tissue-first testing misses patients with alterations detected by Guardant360-first testing.

3X more patients

tested for guideline-recommended alterations vs tissue testing.

1 week

20% more patients

tested faster than tissue with alterations detected by Guardant360-first testing.

Guardant360 tested 95% of patients for the 4 alterations associated with FDA-approved therapies.

Patient advantages

Guardant360 tested 95% of patients vs 31% with tissue for the 4 alterations with FDA-approved therapies.

Disclaimer: This content has not been reviewed by the FDA. Data shown for the performance of Guardant360 laboratory developed test (LDT) does not convey the performance of Guardant360 CDx.

*For the 4 alterations with FDA-approved therapies.
Test with Guardant360 CDx. Take action.
Guideline-recommended genomic results in 7 days

Reliable, guideline-recommended testing
Detects guideline-recommended biomarkers across advanced solid tumors
A simple blood draw enables oncologists to test all advanced solid-tumor patients

Results in 7 days to guide clinical decisions
Easy-to-interpretable report informs first-line decisions and beyond


Disclaimer: For the complete intended use statement for Guardant360 CDx, including companion diagnostic indication, please see the Guardant360 CDx Technical Information:www.guardant360cdx.com/technicalinfo

*Excluding central nervous system cancers