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

myGUARDANT™ PATIENT PORTAL

Be notified when your results are ready

To activate your account, visit patients.guardanthealth.com

*7 days is approximately from when Guardant Health receives the sample to report delivey.

Questions?
We want to hear from you.

Contact Client Services
855.698.8887
clientservices@guardanthealth.com
www.guardanthealth.com

GUARDANT™

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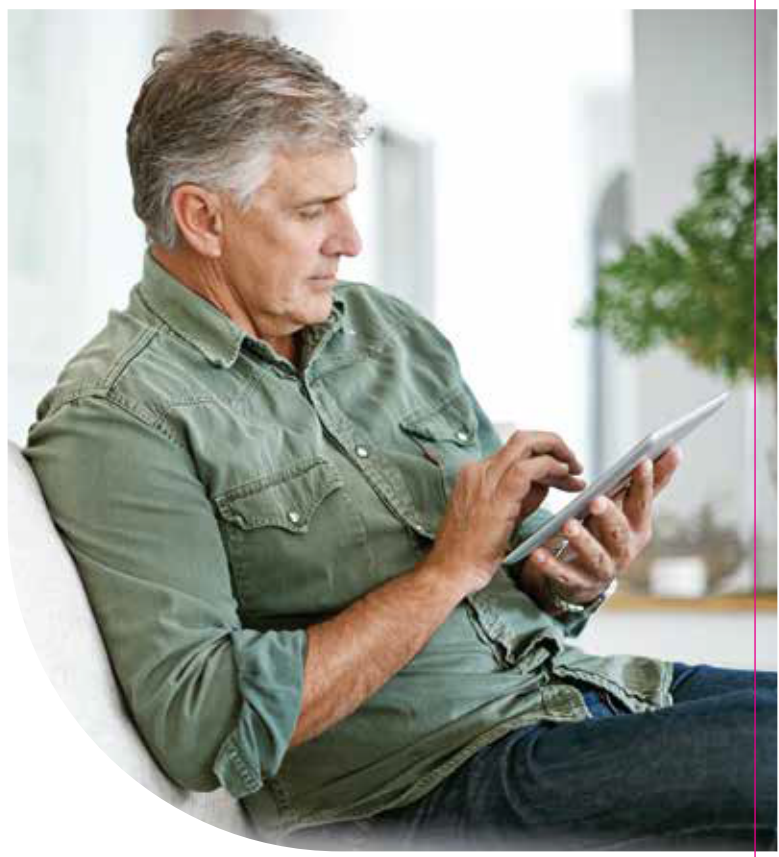
FOR PATIENTS



Inform your treatment plan with a simple blood draw

FDA Approved

COVERED BY MEDICARE

GUARDANT360® CDx
Test. Take Action.

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.

Questions?
We want to hear from you.

Contact Client Services
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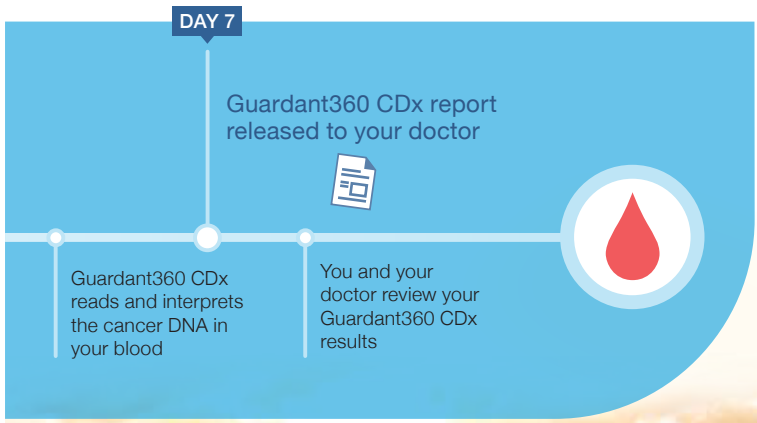
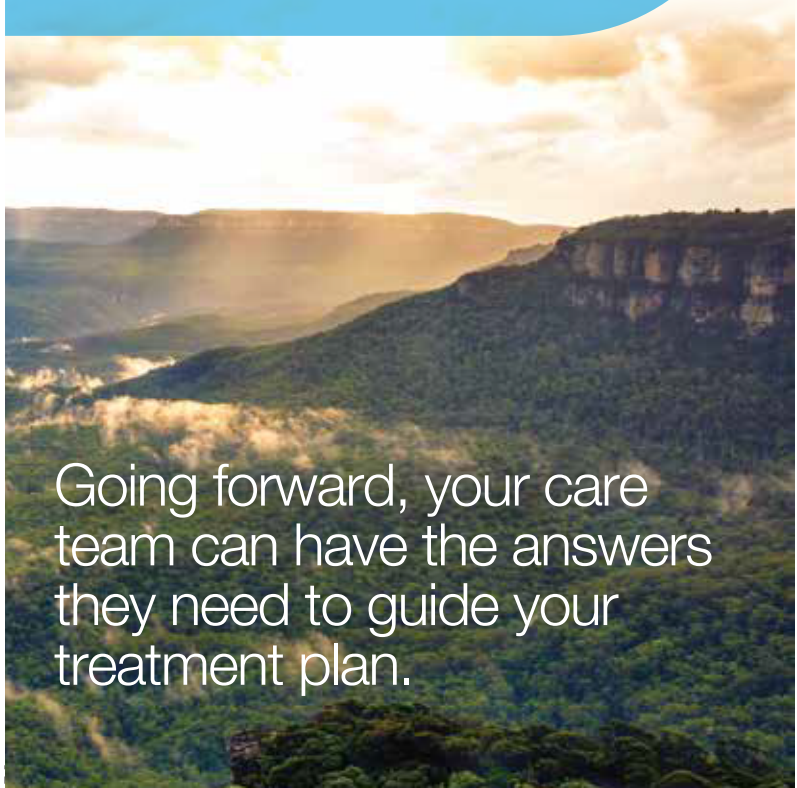
What is Guardant360 CDx?

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.





The right information can make all the difference

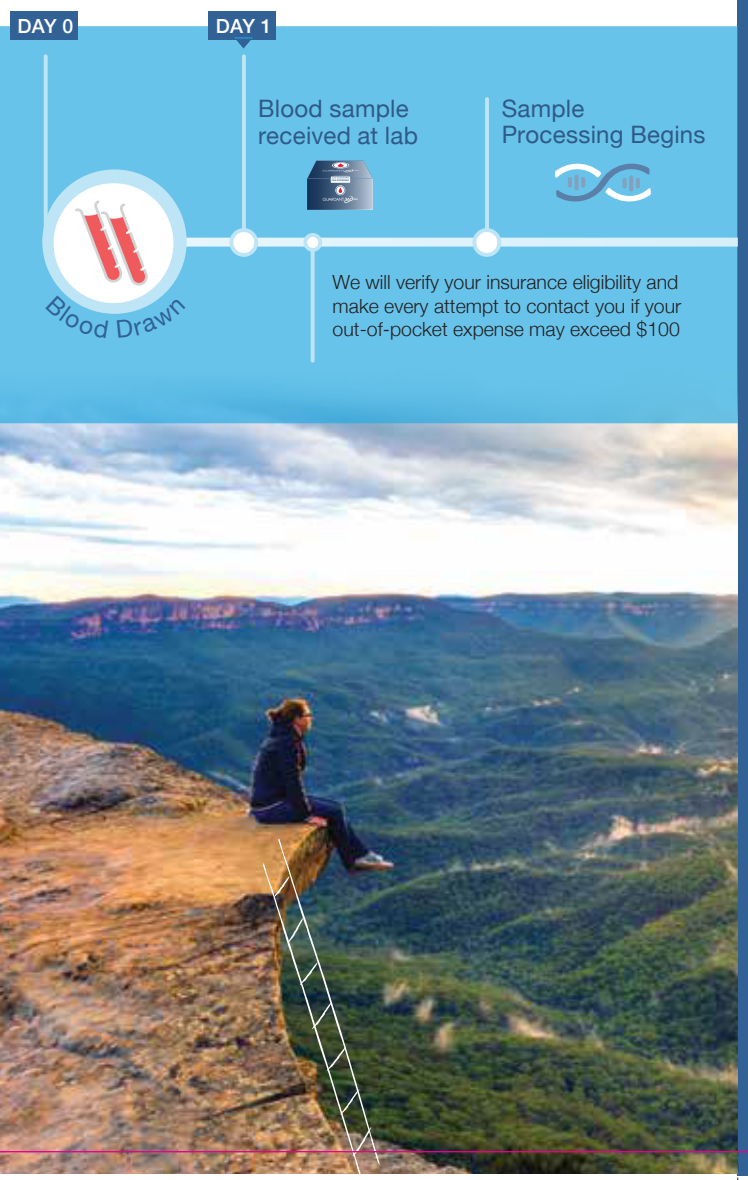
Guardant360 CDx can help

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



PLEASE GIVE THIS TO THE PATIENT

Welcome to

GUARDANT360® CDx

FDA-approved liquid biopsy test

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 delivey.

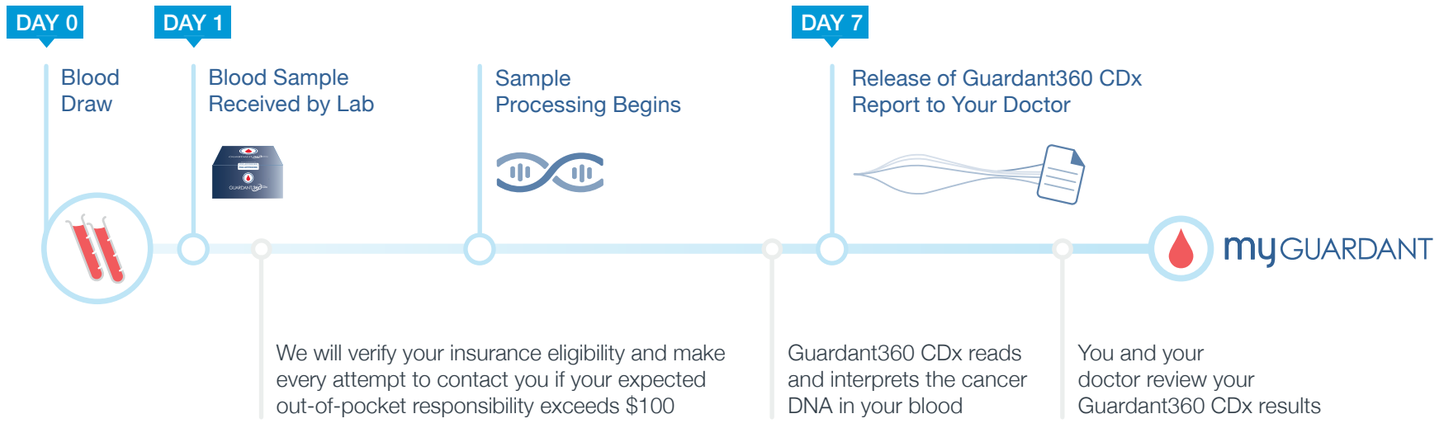
To activate your account, visit
patients.guardanthealth.com
and enter your doctor's last name and date of blood draw

myGUARDANT

Be notified
when your results are ready

*7 days is approximately from when Guardant Health receives the sample to report delivey.

How Guardant360 CDx works



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

COVERED BY MEDICARE

- 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.
- In order for 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:

FDA Approved

Searching for guideline-complete genomic information? Get results faster.

Guide treatment decisions in **7 days**

GUARDANT360® 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

Indication	Biomarker	Therapy
Non-small cell lung cancer (NSCLC)	*EGFR* exon 19 deletions, L858R, and T790M*	TAGRISSO® (osimertinib)

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 reflexed 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 neoplasm. 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

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

Variant Category	PPA (LDT as Comparator Method)
EGFR L858R	98.1%
EGFR Exon 19 deletion	96.7%
EGFR T790M	95.6%

Variant Category	NPA (LDT as Comparator Method)
EGFR L858R	98.0%
EGFR Exon 19 deletion	98.8%
EGFR T790M	97.0%

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 < 0.08% MAF, in patients with *EGFR* L858R <0.09% 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.
- 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

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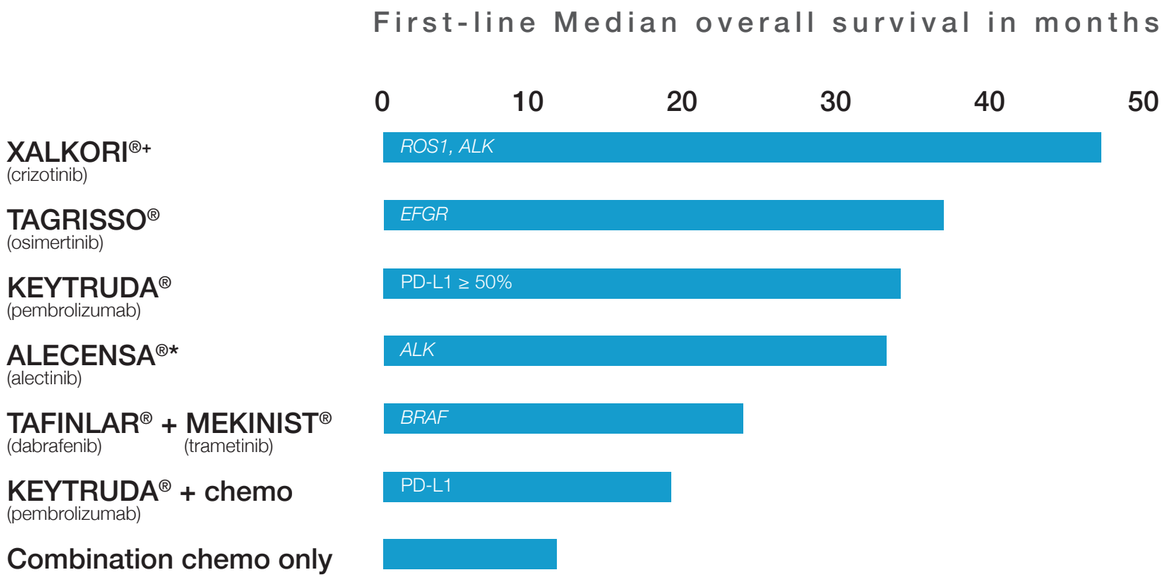
THE ONLY LIQUID BIOPSY COVERED BY MEDICARE ACROSS ADVANCED CANCERS

Today's first-line treatments for advanced NSCLC are more effective than ever before

Immunotherapy and targeted therapies improve overall survival, but only for the right patients[1-7]



NCCN guideline-recommended alterations occur in most patients[8]

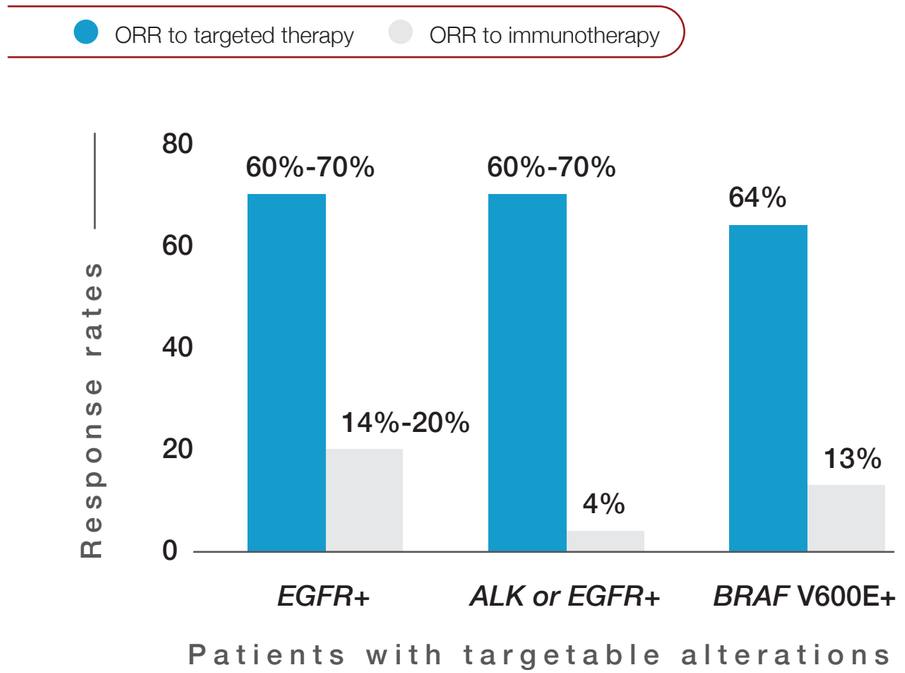
~21% of advanced NSCLC patients have alterations associated with currently FDA-approved drugs[8]

~63% of advanced NSCLC patients have alterations associated with guideline-recommended alterations[8]

*(median PFS) | + Median overall survival data shown refer to patients with ROS1 status

Optimal treatment decisions can only be made after complete genotyping

Immunotherapy is inappropriate for patients with targetable alterations[9-15]



Minimal response to immune checkpoint inhibitors, even when PD-L1 is ≥50%[10-11]

All checkpoint inhibitor labels exclude patients who have *EGFR* and *ALK* alterations[13]

First-line treatment is critical

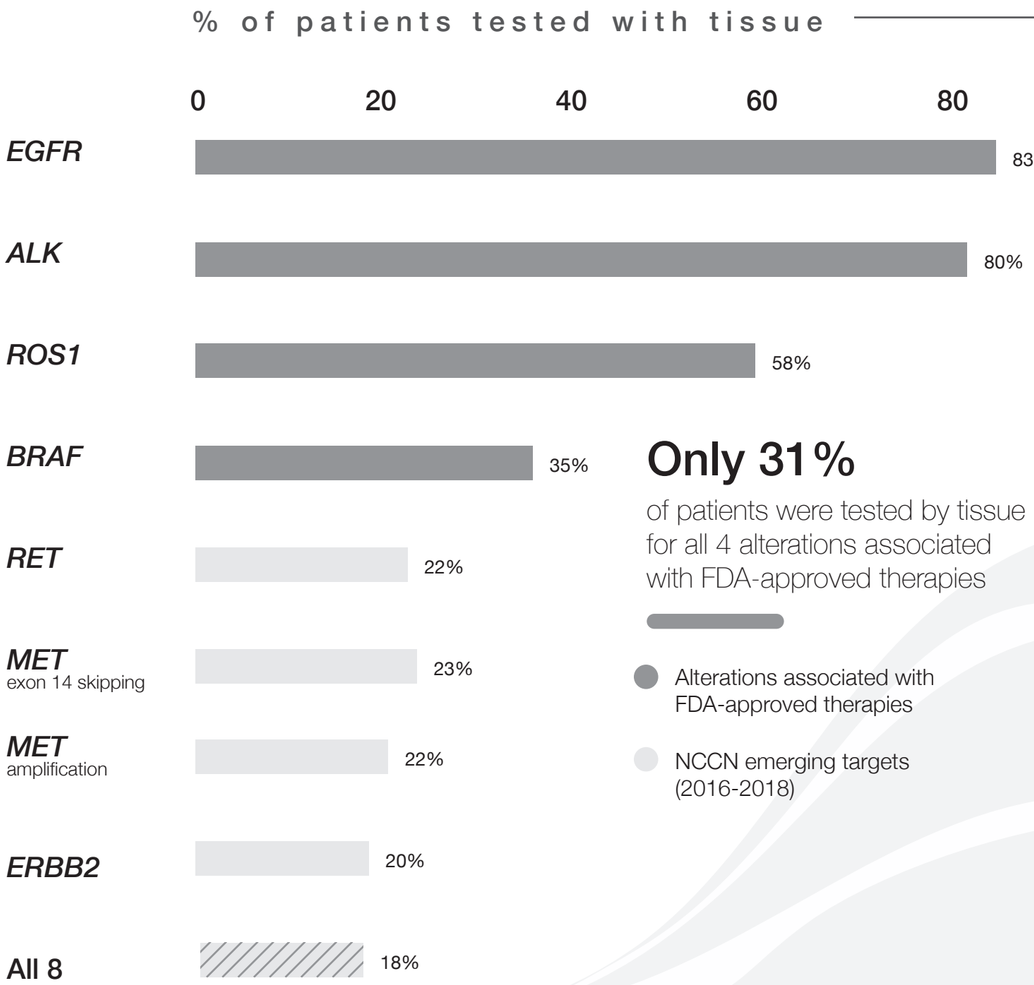
Getting first-line treatment

is critical because only 1 in 2 patients will make it to 2L therapy[16]

Less than 1 in 2 NSCLC patients get complete genotyping from tissue[17-21]

Standard-of-care tissue testing leaves many patients untested for NCCN guideline-recommended alterations[22]

Community practices



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

- Alterations associated with FDA-approved therapies
- NCCN emerging targets (2016-2018)

Tissue challenges exist across practice settings

Comprehensive tissue panels require more tissue than may be available[23]

Academic center

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

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

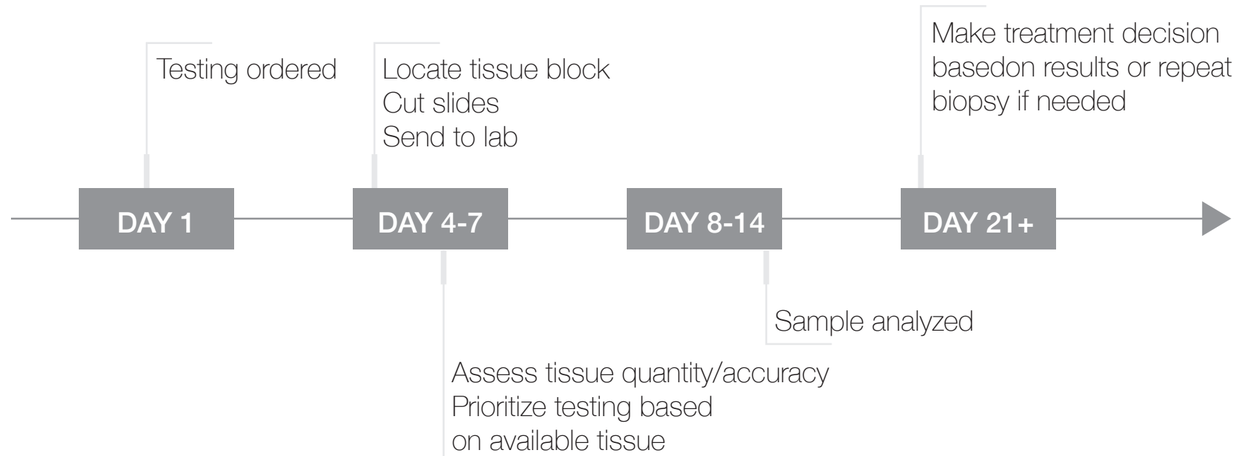
Repeated tissue biopsies expose patients to potential adverse events[24]

Lengthy process

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

Avoid challenges inherent to tissue testing with Guardant360 CDx

Complete genotyping with tissue can take many weeks or longer*



*comprehensive genomic profiling

A simple blood draw easily implemented into your workflow

GUARDANT360 CDx

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

GUARDANT

855.698.8887 Client Services
888.974.4258 Fax
clientservices@guardanthealth.com
www.Guardant360.com

Insurance & Eligibility confirmation

Insurance eligibility confirmation and patient outreach if patient out-of-pocket cost exceeds $100 for all patients

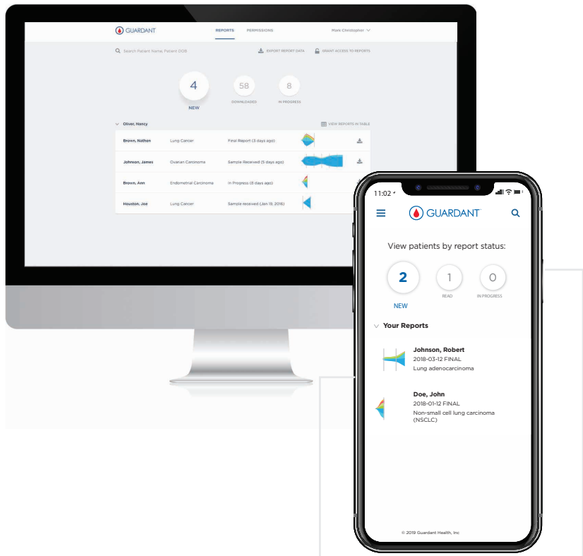
Assessment of financial assistance eligibility regardless of insurance type

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

*Excluding central nervous system tumors

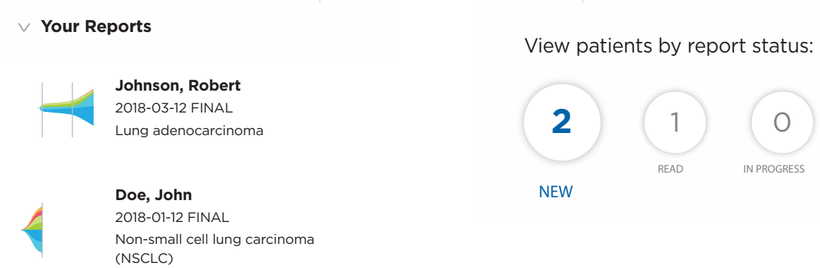
Easy access to reports



Download on the App Store

Access reports via fax, online portal, or app

Get real-time email and in-app notifications when results are ready



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

*From sample receipt to report

GUARDANT360®

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

Complete and fast genomic results you can trust

95%
of patients[22]

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

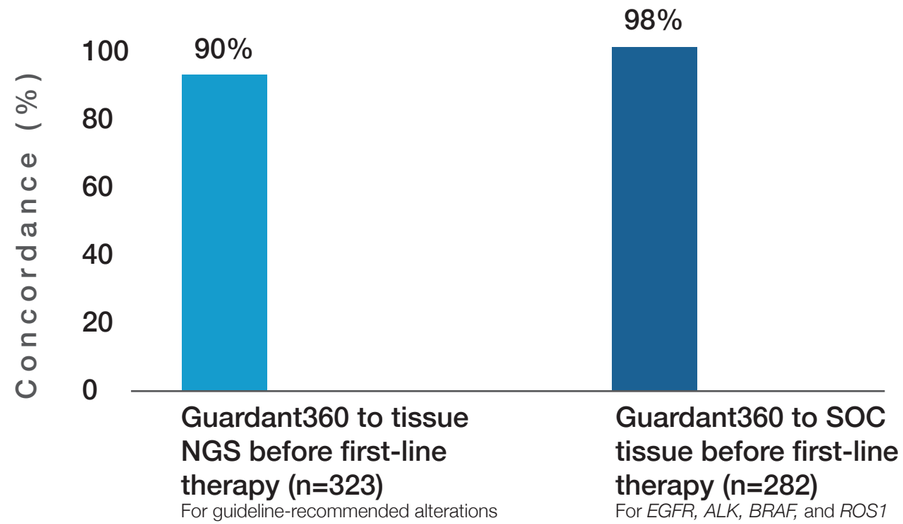
Response rates to therapy selected based on Guardant360 results are consistent with tissue-based studies

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.

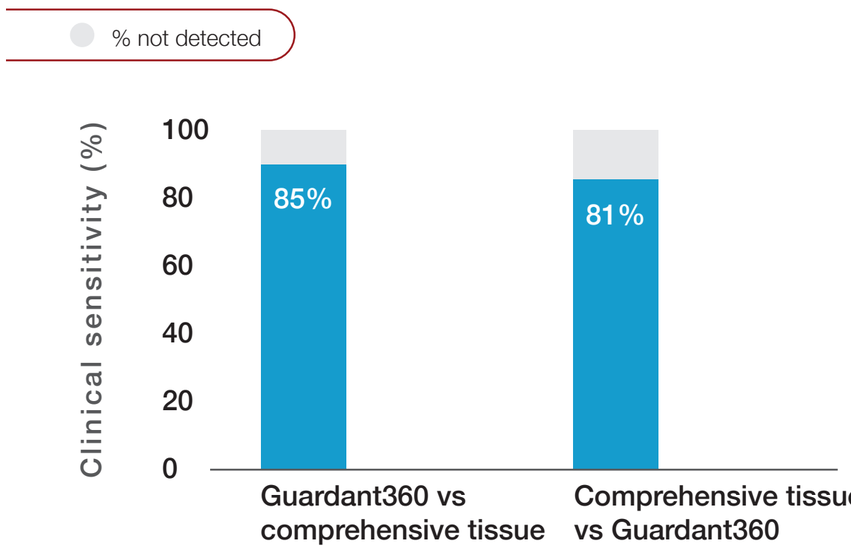
*Excluding central nervous system tumors

Guardant360 LDT has demonstrated consistently high concordance to tissue testing

Evidence from multiple prospective clinical studies[22-23]



15%-20% of the time tissue misses what liquid finds and vice versa[25]



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

NILE study found Guardant360 LDT enabled increased patient testing, more alterations detected, faster results

Key Findings[22]

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*

Patient advantages

3X more patients
tested for guideline-recommended alterations* vs tissue testing

1 week
faster than tissue

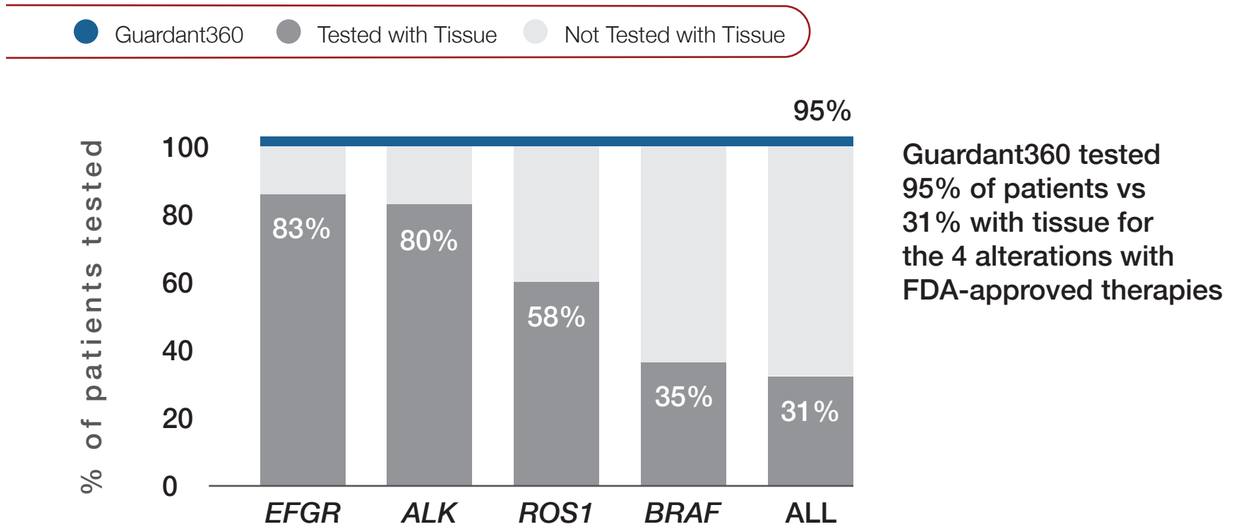
20% more patients
with alterations detected by Guardant360-first testing

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.

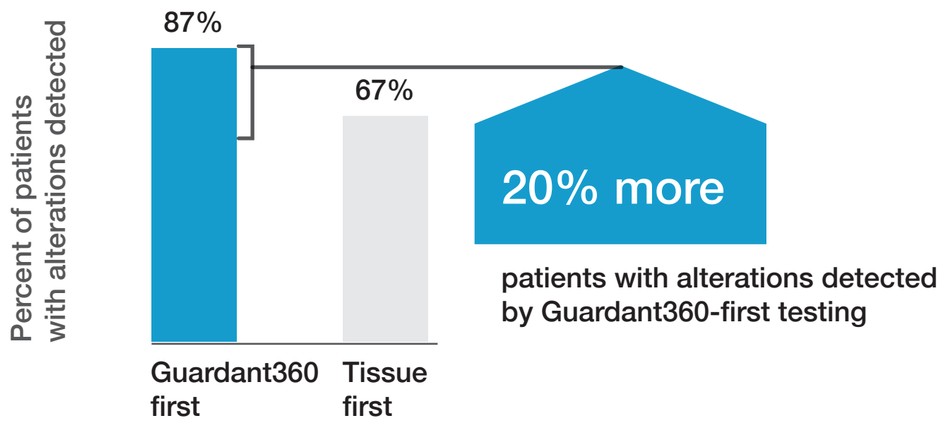
*For the 4 alterations with FDA-approved therapies

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

Guardant360 tested 95% of patients for the 4 alterations associated with FDA-approved therapies[22]



Tissue-first testing misses patients with alterations[22]



GUARDANT360 CDx

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-interpret report informs first-line decisions and beyond

FDA Approved

THE ONLY LIQUID BIOPSY COVERED BY MEDICARE ACROSS ADVANCED CANCERS*

*Excluding central nervous system cancers

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

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D-000448 R2

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