

# Guardant360® CDx

**Category:**

Best Medical Technology

**Company Name:**

Guardant Health

**Product/Solution Name:**

Guardant360® CDx

**Compound/Tech Name:**

Guardant360® CDx

**Trade Name:**

Guardant Health

**Corporate Name:**

N/A

**Date of Approval:**

2020-08-07

**Indications:**

Guardant360® is a blood test for comprehensive genomic profiling (CGP) of all solid tumors for patients with advanced cancer. With a simple blood draw, this test, known as a liquid biopsy, provides results within ten days and enables healthcare providers to match patients with the right targeted therapy, which can significantly extend survival.<sup>1-7</sup>

On August 7, 2020, Guardant360 CDx became the first comprehensive liquid biopsy test to receive approval by the U.S. Food and Drug Administration.<sup>8</sup> That same day, the test received FDA approval as a companion diagnostic to identify patients with non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) alterations who may benefit from treatment with TAGRISSO® (osimertinib).<sup>9</sup> In May 2021, Guardant360 CDx became the first and only FDA-approved companion diagnostic

for use in patients with advanced NSCLC with EGFR Exon 20 insertion mutations who may benefit from RYBREVANT (amivantamab-vmjw)<sup>10</sup> and for use in advanced NSCLC patients who harbor the KRAS G12C mutation and may benefit from LUMAKRAS<sup>™</sup> (sotorasib).<sup>11</sup> In 2022, the test received FDA approval as a companion diagnostic to select patients with HER2-mutant NSCLC for treatment with ENHERTU® (fam-trastuzumab deruxtecan-nxki) and in 2023, it was approved as the first companion diagnostic for ORSERDUTM (elacestrant) for treatment of patients with ESR1 mutations in ER+, HER2- advanced or metastatic breast cancer.

This year, it is estimated that there will be about 1.9 million new cancer cases diagnosed and 609,360 cancer deaths in the United States. This equates to about 1,670 deaths a day.<sup>12</sup> The Guardant360 CDx blood test is being used to successfully enable more patients with advanced cancer to get appropriate therapy more quickly.<sup>13</sup>

Guardant Health's tests are used by more than 12,000 oncologists around the world to guide treatment decisions across solid tumor cancers, and by pharmaceutical companies and academic researchers in clinical trials to accelerate precision medicine drug development.

## **Therapeutic Areas:**

Targeted cancer therapies, which are facilitated by CGP (also known as tumor mutation profiling), are prolonging survival times and improving quality of life<sup>1</sup> and outcomes for patients with late-stage cancer.<sup>2</sup> Because cancer genomes are complex, CGP offers the greatest insight into optimal treatment.<sup>5</sup> In a 2020 study published in *Cancers (Basel)*<sup>6</sup>, "CGP identified at least one potentially clinically actionable genomic alteration in 95% of all patients tested."

For patients diagnosed with late-stage cancer, the longer treatment is delayed, the poorer the prognosis,<sup>1-4</sup> so capturing a comprehensive picture of the disease as soon as possible is critical to get them started on the most appropriate first-line treatment quickly.

The most expedient way to ensure patients receive complete tumor mutation profiling is with a blood test like Guardant360 CDx. The ability to identify tumor mutations quickly and accurately in a minimally invasive, cost-effective, and repeatable way has a significantly favorable impact on both patients and providers. Adopting liquid biopsy as a standard of care in certain advanced cancers like non-small cell lung cancer (NSCLC) is appealing to oncologists for several reasons—e.g., less invasive than a tissue biopsy and rapid results—but perhaps the most convincing one is the superiority in the detection of certain biomarkers, or mutations, that can be used to identify the best therapy.<sup>7</sup> Identifying more of these mutations that are driving the cancer ultimately leads to improved patient care and more favorable outcomes.<sup>8-13</sup>

Since being introduced as a laboratory developed test in 2014, the Guardant360 liquid biopsy has become widely accepted for blood-based CGP with more than 450 peer-reviewed publications. It has been used by more than 12,000 oncologists, and more than 500,000 tests have been performed to date.<sup>14</sup>

Guardant360 is just the beginning. Learning from this test for late-stage cancer has enabled Guardant Health to develop tests for use across the entire continuum of cancer care – including screening tests to detect possible cancer in patients before they have symptoms and minimal residual disease tests to identify early-stage cancer patients who may be at risk for the disease returning after surgery.

## **General Information File Document upload:**

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## **Background information and need for drug / device:**

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## **Background File Document upload:**

N/A

## **History of the development of the solution/product:**

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## **Development File Document upload:**

N/A

## **Why this drug or device is innovative, the broad implications for future research, and/or how it will improve the human condition:**

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## **Innovation File Document upload:**

**Please provide appropriate references (PubMed, Abstract, Website):**

References for Indications Section

Shaw AT, Riely GJ, Bang Y-J, et al. Crizotinib in ROS1-rearranged advanced non-small-cell lung cancer (NSCLC): updated results, including overall survival, from PROFILE 1001. *Annals of Oncology*. 2019;30(7):1121-1126.

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Cui W. et al, IASLC, VP01.17. Clinical Utility of ctDNA Next Generation Sequencing (NGS) for Target Identification in Diagnostic and Acquired Resistance Settings in Metastatic NSCLC – A Single Centre Experience. Oct 2020.

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