

1 **Saul Perloff** (Cal. Bar 157092)  
saul.perloff@nortonrosefulbright.com  
2 **NORTON ROSE FULBRIGHT US LLP**  
111 W. Houston Street, Suite 1800  
3 San Antonio, Texas 78205-3792  
Telephone (210) 224-5575  
4 Telecopier (210) 270-7205  
5 Attorneys for Plaintiff  
GUARDANT HEALTH, INC.  
6  
7  
8

9 **UNITED STATES DISTRICT COURT**  
10 **NORTHERN DISTRICT OF CALIFORNIA**

11 **GUARDANT HEALTH, INC.,**  
a Delaware corporation,

12 Plaintiff,

13 vs.

14 **NATERA, INC.,**  
a Delaware corporation,

15 Defendant.  
16  
17

Case No. 3:21-cv-04062

**ORIGINAL COMPLAINT**

**JURY TRIAL DEMANDED**

18 Plaintiff Guardant Health, Inc. (“Guardant” or “Plaintiff”) files this Original Complaint  
19 against Defendant Natera, Inc. (“Natera” or “Defendant”) and in support thereof, alleges as  
20 follows:

21 **I. INTRODUCTION**

22 1. This case concerns Plaintiff’s Guardant Reveal™ (“Reveal”) liquid biopsy cancer  
23 assay for early-stage colorectal cancer (CRC) patients, and Defendant Natera’s campaign of false  
24 and misleading advertising directed at this important and innovative diagnostic product. As the  
25 world’s leading provider of comprehensive circulating tumor DNA (ctDNA) assays for clinical  
26 use, Guardant’s oncology platform—including its gold-standard Guardant360®, Guardant360®  
27 CDx, and GuardantOMNI® assays—have helped improve clinical outcomes, while lowering  
28 healthcare costs, for advanced stage cancer patients around the world.

2. Leveraging its patented technology, vast data sets, and advanced analytics, Guardant recently launched Reveal, a plasma-only liquid biopsy test that detects residual and recurrent CRC in about 7 days from a simple blood draw. For oncologists, Reveal improves the management of early-stage CRC patients by detecting ctDNA in plasma after surgery, enabling doctors to identify patients with residual CRC who may benefit from post-surgery chemotherapy (adjuvant chemotherapy), months earlier than current standard-of-care tests permit. Reveal is the first test for minimal residual disease (MRD) detection that detects ctDNA in the plasma of CRC patients following treatment *without the need for a tissue sample and sequencing* to determine the particular mutations that were present in the patient's tumor. Reveal achieves outstanding sensitivity (91%) for predicting recurrence of CRC disease.

3. With little or no concern for the CRC patients who could be harmed, Natera has undertaken a campaign of misinformation to convince customers and potential customers, including oncologists and other physicians, cancer researchers, health care institutions, biopharmaceutical companies, and genetic laboratories, to avoid using Reveal in favor of Natera's own Signatera™ ("Signatera"), a tumor-dependent assay. In its commercial advertising and promotion, Natera makes literally false and misleading statements that disparage Guardant's new assay, and falsely asserts that Signatera is superior to Reveal across a variety of metrics, including sensitivity,<sup>1</sup> failure rate,<sup>2</sup> negative predictive value (NPV),<sup>3</sup> and Hazard Ratio,<sup>4</sup> among other categories. These claims are false. Natera combines outright misrepresentations with scientifically unfounded comparisons based on cherry-picked metrics, data artifacts, and

---

<sup>1</sup> "Sensitivity" refers to the assay's ability to identify which patients will develop recurrences based on MRD detection by ctDNA assay. A higher percentage indicates a test is more sensitive.

<sup>2</sup> "Failure rate" refers to the percentage of time a ctDNA assay fails to provide a result at all, whether positive or negative. For any test, a lower failure rate is more desirable.

<sup>3</sup> "NPV" refers to the assay's ability to correctly predict which patients will subsequently not develop a recurrence of CRC (i.e., a "negative" test result means CRC will not recur).

<sup>4</sup> The "Hazard Ratio" refers to a comparison between the recurrence rate over time in CRC patients who tested positive for MRD by ctDNA assay, to the recurrence rate in CRC patients who tested negative for MRD by ctDNA. A larger hazard ratio suggests that the assay is potentially more useful in successfully distinguishing CRC patients whose cancers will or will not recur.

1 noncomparable clinical studies to exaggerate the purported benefits of Signatera while  
2 inaccurately denigrating Reveal. In truth, Reveal has important clinical advantages over  
3 Signatera—including its superior landmark sensitivity, its availability for patients from whom  
4 tumor samples are unavailable, and its faster initial turnaround time from sample collection to  
5 assay results—all of which Natera ignores.

6 4. Guardant seeks to enjoin Natera from continuing to make or disseminate false and  
7 misleading statements about the performance of Reveal and Signatera; to require Natera to  
8 retract, remove, and correct these false and misleading advertising claims; and to recover  
9 damages and other relief for the harm that Natera has inflicted on Guardant.

## 10 II. PARTIES

11 5. Plaintiff Guardant is a Delaware corporation having its principal place of business  
12 at 505 Penobscot Dr., Redwood City, California 94063.

13 6. Guardant was founded in 2012 by pioneers in DNA sequencing and cancer  
14 diagnostics. Since its inception, Guardant has focused its expertise on the development of liquid  
15 biopsy assays for cancer. It was the first company to develop and commercialize a  
16 comprehensive liquid biopsy assay to identify genomic biomarkers for advanced solid tumors  
17 using cell-free ctDNA, from simple, non-invasive blood draws.

18 7. Today, Guardant is a leading precision oncology company focused on helping  
19 conquer cancer globally through the use of its proprietary blood tests, vast data sets, and  
20 advanced analytics. The Guardant oncology platform leverages its capabilities to drive  
21 commercial adoption, improve patient clinical outcomes, and lower healthcare costs across all  
22 stages of the cancer care continuum. Guardant Health has commercially launched the liquid  
23 biopsy-based Guardant360®, Guardant360® CDx, and GuardantOMNI® tests for advanced  
24 stage cancer patients, and recently launched its Reveal test for early-stage CRC patients.

25 8. Defendant Natera is a Delaware corporation having its principal place of business  
26 at 13011 McCallen Pass, Building A, Suite 100 Austin, Texas 78753, and offices at 201  
27 Industrial Rd., San Carlos, California 94070. Natera may be served with process by serving a  
28 copy of this Complaint on its Registered Agent: National Registered Agents, Inc., 1209 Orange

1 Street, Wilmington, Delaware 19801.

2 9. Natera markets and sells Signatera, a product it describes as a “personalized,  
3 tumor-informed assay optimized to detect circulating tumor DNA (ctDNA) for molecular  
4 residual disease (MRD) assessment and recurrence monitoring for patients previously diagnosed  
5 with cancer.” Signatera competes with Reveal in the market for ctDNA assays that can be used  
6 after surgery on CRC patients, to detect recurrences and evaluate the need for adjuvant  
7 chemotherapy.

### 8 **III. JURISDICTION AND VENUE**

9 10. This is an action for false advertising under Section 43(a) of the Lanham Act, 15  
10 U.S.C. § 1125(a); for false advertising in violation of Cal. Bus. & Prof. Code § 17500 et seq.; for  
11 unlawful trade practices in violation of Cal. Bus. & Prof. Code § 17200 et seq.; and for unfair  
12 competition in violation of the common law of California and other states in which Defendant is  
13 conducting its activities.

14 11. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C.  
15 §§ 1331 and 1338 and 15 U.S.C. §§ 1051, et seq.

16 12. This Court has jurisdiction over Plaintiff’s state law claims pursuant to 28 U.S.C.  
17 § 1367 and the doctrine of supplemental jurisdiction.

18 13. The exercise of personal jurisdiction in California is proper both because of  
19 Defendant’s ongoing and systematic contact with California and the Northern District of  
20 California, including its maintenance of a regular place of business in the District, and because  
21 acts giving rise to Plaintiff’s causes of action have occurred in the Northern District of  
22 California. Specifically, Natera markets, promotes, advertises, offers for sale, sells, and/or  
23 distributes Signatera to customers including oncologists and other physicians, cancer researchers,  
24 health care institutions, biopharmaceutical companies, genetic laboratories, and/or others  
25 throughout the United States, including in the Northern District of California. Defendant has  
26 purposefully and voluntarily placed Signatera into the stream of commerce with the expectation  
27 that this product will be purchased by customers in the Northern District of California.  
28 Furthermore, Natera falsely and misleadingly advertises Signatera to customers, including

1 oncologists, pathologists, additional physicians, health care institutions, pharmaceutical  
2 companies, and/or others throughout the United States, including in the Northern District of  
3 California.

4 14. Venue is proper in the Northern District of California pursuant to 28 U.S.C.  
5 § 1391.

#### 6 IV. FACTUAL BACKGROUND

##### 7 A. Early Identification of At-Risk Patients is a Key to Preventing Recurrence of 8 Colorectal Cancer and Prolonging Survival

9 15. Colorectal cancer (CRC) is the third most commonly diagnosed cancer and the  
10 second leading cause of cancer death in the United States in both men and women. While a  
11 majority of patients are diagnosed with early-stage disease, nearly a third of patients whose CRC  
12 spreads into adjacent tissues and lymph nodes will die from their disease within five years.

13 16. Surgery alone is often curative for early-stage CRC, and in later-stage cases,  
14 adjuvant chemotherapy after surgery can reduce the risk of recurrence. However, clinicians have  
15 had very limited means of identifying patients that require adjuvant chemotherapy. Thus, the  
16 development of effective clinical tests to identify CRC patients with MRD—i.e., a small number  
17 of CRC cells remaining in the body that can later multiply and cause recurrence of the disease—  
18 after surgery has long been recognized as a need, to help doctors both identify patients who may  
19 benefit from additional therapy, and avoid administering unnecessary and toxic treatment to  
20 patients who will not benefit from it.

21 17. Because residual cancer cells that remain in the body following treatment  
22 typically cause no physical signs or symptoms and are present at very low levels that are  
23 undetectable with standard techniques, detecting and monitoring MRD has required development  
24 of advanced and highly sophisticated technologies with the requisite precision and sensitivity for  
25 clinical decision-making. Reveal provides that sophisticated technology.

##### 26 B. Liquid Biopsy Technology Allows Assessment of MRD by Detecting Circulating 27 Tumor DNA in Blood

28 18. Human blood contains fragments of DNA that are shed into the bloodstream by

# Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

## Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

## Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

## Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

## API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

## LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

## FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

## E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.