

**IN THE UNITED STATES DISTRICT COURT  
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA**

NATERA, INC.,

Plaintiff,

v.

NEOGENOMICS LABORATORIES, INC.,

Defendant.

C.A. No. 1:23-CV-629-CCE-JLW

**NEOGENOMICS LABORATORIES, INC.'S THIRD REQUESTS FOR PRODUCTION**

Pursuant to Rules 26 and 34 of the Federal Rules of Civil Procedure, Defendant, NeoGenomics Laboratories, Inc. (“NeoGenomics” or “Defendant”) hereby requests that Plaintiff Natera, Inc. (“Natera” or “Plaintiff”), by officer or agent of Natera, produce each document and thing within its possession, custody, or control that is responsive to the individual requests set forth below, within thirty (30) days of service, on NeoGenomics’ counsel.

**DEFINITIONS**

The following definitions apply to the Requests below.

1. “Natera” or “Plaintiff” mean Natera, Inc. and includes each of its officers, directors, members, managers, agents, consultants, contractors, employees, attorneys, accountants, partners, corporate parents, subsidiaries, affiliates, divisions, predecessors-in-interest (including but not limited to Gene Security Network), or successors-in-interest, and any person or entity, past or present, who acts on Natera, Inc.’s behalf or purports to act on Natera, Inc.’s behalf.
2. “NeoGenomics” or “Defendant” means NeoGenomics Laboratories, Inc.
3. “454 Patent” means U.S. Patent No. 11,530,454, entitled “Detecting Mutations and Ploidy in Chromosomal Segments.”

4. “‘035 Patent” means U.S. Patent No. 11,519,035, entitled “Methods for Simultaneous Amplification of Target Loci.”

5. “‘596 Patent” means U.S. Patent No. 11,319,596, entitled “Detecting Mutations and Ploidy in Chromosomal Segments.”

6. “Asserted Patents” means the ‘454 Patent, the ‘035 Patent, and the ‘596 Patent individually and collectively.

7. “Asserted Claims” means the claims of the Patents-In-Suit that Natera asserts NeoGenomics has infringed.

8. “Accused Product” means RaDaR, and any other products, devices, tools, or tests that Natera alleges infringe any asserted claim of the Asserted Patents that NeoGenomics has allegedly made, used, sold, offered for sale in the United States, or imported into the United States.

9. “Lawsuit” means the case styled *Natera, Inc. v. NeoGenomics Laboratories, Inc.*, C.A. No. 1-23-cv-629, pending in the United States District Court for the Middle District of North Carolina.

10. “Document” is synonymous in meaning and equal in scope to term “documents or electronically stored information” as used in Federal Rule of Civil Procedure 34(a)(1)(A) and includes, without limitation, any written, printed, recorded, electronic, or graphic matter that is or has been in Natera’s actual or constructive possession or control, regardless of the medium on which it is produced, reproduced, or stored, and includes, without limitation, all originals, copies, drafts (sent or unsent), or other non-conforming copies of every kind.

11. “Prior Art” has the same meaning as used in 35 U.S.C. §§ 102 and 103, and includes any patent, printed publication, prior knowledge, prior use, prior sale or offer for sale, or other act, event, or document defined in 35 U.S.C. §§ 102 and 103, taken singularly or in combination.

12. “MRD” means Minimal Residual Disease.
13. “Communication” means the transmittal of information (in the form of facts, ideas, inquiries, opinions, or otherwise) between individuals or entities, whether oral, written, electronic, in-person, telephonically, directly, through an intermediary, or otherwise.
14. “Refer,” “relate,” “relating,” “respecting,” or “concerning” shall be construed in the broadest sense to mean information (a) that contains or comprises any representations, requests, demands, studies, or analyses referred to in these Requests; or (b) information that discusses, mentions, or refers, whether directly or indirectly, to the subject matter of the Request.
15. “Related Patent” or “Related Patents” means any U.S. patent, non-U.S. patent, U.S. patent application, including provisionals, or non-U.S. patent application, including provisionals, that claims priority to or from, shares a common claim of priority with, or shares all or substantially all of its specification with the Asserted Patents.
16. “Molecular Diagnostic Services Program” or “MolDX®” means the Centers for Medicare and Medicaid Services’ program administered by Palmetto GBA to review all new test/assay clinical information to determine if a test meets Medicare’s reasonable and necessary requirement.
17. “Signatera” means Natera’s MRD assay launched in 2017, and all subsequent versions and updates thereto.
18. “RaDaR 1.1” means NeoGenomics’ MRD assay.

### **INSTRUCTIONS**

The following instructions apply to the Requests below.

1. The Requests below seek Documents and Communications within Natera’s possession, custody, or control, and Natera must produce non-privileged, responsive Documents

and Communications that are in its possession, custody, or control.

2. Natera shall produce all electronically stored information (“ESI”) in standard, single-page Group IV TIFF format with searchable text and metadata in a Concordance or similar load file. Natera shall produce any spreadsheet or presentation files, including Microsoft Access, Excel, and PowerPoint files, as well as audio, audiovisual, and video files, in their native formats. Provide all hard copy documents as image files with searchable OCR text and unitize the hard copy documents to the extent possible (*i.e.*, multi-page documents shall be produced as a single document and not as several single-page documents). Natera shall produce hard copy documents as it keeps them, reflecting attachment relationships between documents and information about the file folders within which Natera found the document. Natera shall produce the metadata for any responsive ESI with the responsive Data, including the following fields: custodian, author(s), recipient(s), blind copy recipient(s), subject, file sent date/time, file creation date/time, file modification date/time, file last accessed date/time, beginning Bates, ending Bates, parent beginning Bates, attachment(s) beginning Bates, hash value, application type, file type, file name, file size, file path, and folder path. Natera should accompany documents you produce in native format with a native link field.

3. If no documents or things exist that are responsive to a particular Request, then Natera should so state in your response to the Request.

4. If Natera finds the meaning of any term in any Request unclear or ambiguous, then Natera should assume a reasonable meaning, state what the assumed meaning is in its response, and respond to the Request according to that meaning.

5. Unless otherwise specified below, the relevant time period for these Requests is January 1, 2017 to the present.

## **REQUESTS FOR PRODUCTION**

### **REQUEST FOR PRODUCTION NO. 105:**

All documents and communications concerning inquiries from third parties about litigation against NeoGenomics or RaDaR 1.1, the parties' Confidential Partial Settlement Agreement executed on September 20, 2024, and/or the Stipulated Order and Permanent Injunction (ECF No. 329 (09/23/2024)).

### **REQUEST FOR PRODUCTION NO. 106:**

All documents and communications concerning changing the National Comprehensive Cancer Network's ("NCCN") Clinical Practice Guidelines in Oncology to include circulating tumor DNA diagnostic testing.

### **REQUEST FOR PRODUCTION NO. 107:**

All documents and communications concerning Natera's efforts to change the National Comprehensive Cancer Network's ("NCCN") Clinical Practice Guidelines in Oncology to include circulating tumor DNA-based diagnostic testing, including, without limitation, outreach to NCCN guideline committee members, applications and/or submissions to update the NCCN guidelines, and outreach to key opinion leaders to garner support for changing the NCCN guidelines.

### **REQUEST FOR PRODUCTION NO. 108:**

All documents and communications concerning Natera's outreach to the National Comprehensive Cancer Network ("NCCN") regarding the inclusion of circulating tumor DNA-based in the NCCN's Clinical Practice Guidelines in Oncology.

**REQUEST FOR PRODUCTION NO. 109:**

All documents and communications concerning Natera's outreach to the NCCN Guideline Panel members regarding the inclusion of circulating tumor DNA diagnostic testing in the NCCN's Clinical Practice Guidelines in Oncology.

**REQUEST FOR PRODUCTION NO. 110:**

All documents and communications concerning Natera's outreach to key opinion leaders advocating for the inclusion of circulating tumor DNA-based diagnostic testing in the NCCN's Clinical Practice Guidelines in Oncology.

**REQUEST FOR PRODUCTION NO. 111:**

All documents and communications concerning submissions to the NCCN Guidelines Panels, including, without limitation, the submission of formal guideline requests, submission of discussion requests, and/or comments for guidelines discussion, regarding the inclusion of circulating tumor DNA-based diagnostic testing in the NCCN's Clinical Practice Guidelines in Oncology.

**REQUEST FOR PRODUCTION NO. 112:**

All documents and communications concerning Natera's July 24, 2023 submission to the NCCN Guidelines Panel on Bladder Cancer.

**REQUEST FOR PRODUCTION NO. 113:**

All documents and communications concerning Natera's July 28, 2021 submissions to the NCCN Guidelines Panel on Breast Cancer.

**REQUEST FOR PRODUCTION NO. 114:**

All documents and communications concerning Natera's July 31, 2023 submission to the NCCN Guidelines Panel on Breast Cancer.

**REQUEST FOR PRODUCTION NO. 115:**

All documents and communications concerning Natera's July 13, 2020 submissions to the NCCN Guidelines Panel on Colon Cancer.

**REQUEST FOR PRODUCTION NO. 116:**

All documents and communications concerning Natera's July 13, 2020 submissions to the NCCN Guidelines Panel on Rectal Cancer.

**REQUEST FOR PRODUCTION NO. 117:**

All documents and communications concerning Natera's July 19, 2022 submission to the NCCN Guidelines Panel on Rectal Cancer.

**REQUEST FOR PRODUCTION NO. 118:**

All documents and communications concerning Natera's July 19, 2022 submission to the NCCN Guidelines Panel on Colon Cancer.

**REQUEST FOR PRODUCTION NO. 119:**

All documents and communications concerning Natera's June 22, 2023 submission to the NCCN Guidelines Panel on Rectal Cancer.

**REQUEST FOR PRODUCTION NO. 120:**

All documents and communications concerning Natera's June 22, 2023 submission to the NCCN Guidelines Panel on Colon Cancer.

**REQUEST FOR PRODUCTION NO. 121:**

All documents and communications concerning Natera's July 28, 2023 submission to the NCCN Guidelines Panel on Esophageal Cancer.

**REQUEST FOR PRODUCTION NO. 122:**

All documents and communications concerning Natera's July 28, 2023 submission to the

NCCN Guidelines Panel on Gastric Cancer.

**REQUEST FOR PRODUCTION NO. 123:**

All documents and communications between Natera and MolDX® program administrators concerning or referring to NeoGenomics and/or RaDaR.

This the 4th day of March 2025

/s/ Matthew R. Stephens

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*Counsel for NeoGenomics Laboratories, Inc.*  
*\*Special Appearance under Local Civil Rule 83.1(d)*

**CERTIFICATE OF SERVICE**

I, the undersigned, hereby certify that on March 4, 2025, a true and correct copy of the foregoing **NEOGENOMICS LABORATORIES, INC.'S THIRD REQUESTS FOR PRODUCTION (NOS. 105-123)** was served via electronic mail upon the following:

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*/s/ Moe San*

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