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**UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA**

Genolab, Inc.,

Plaintiff,

v.

Thermo Fisher Scientific, Inc., and
Thermo Fisher Financial Services, Inc.

Defendants.

Case No. 22-cv-

COMPLAINT

Plaintiff Genolab, Inc., by and through its attorneys, for its Complaint against Defendants Thermo Fisher Scientific, Inc. and Thermo Fisher Financial Services, Inc., alleges, on knowledge as to its own actions, and otherwise upon information

1 and belief, as follows:

2 **PARTIES**

3
4 1. Genolab, Inc. is a corporation that is incorporated in California, with its
5 principal place of business in Los Angeles, CA.

6
7 2. Thermo Fisher Scientific, Inc. (“Thermo Fisher”) is a corporation that is
8 incorporated in Delaware, with its principal place of business in Waltham, MA.

9
10 3. Thermo Fisher Financial Services, Inc. (“TFFS”) is a corporation that
11 is incorporated in Delaware, with its principal place of business in Waltham, MA.
12 Upon information and belief, TFFS is owned in its entirety by Thermo Fisher.

13 **JURISDICTION AND VENUE**

14
15 4. This Court has subject matter jurisdiction over this action pursuant to
16 28 U.S.C. § 1332(a)(1), in that this is an action between citizens of different States,
17 and the amount in controversy exceeds \$75,000.00, exclusive of interest and costs.

18
19 5. Venue is proper in this district under 28 U.S.C. § 1391(b)(2), in that a
20 substantial part of the events giving rise to the claims occurred in this district.

21 **FACTS**

22
23 6. Genolab is a California-based organization that performs cutting-edge,
24 industry-leading molecular and genetic testing. Genolab is CLIA-certified by the
25 Centers for Medicare and Medicaid Services (CMS).

26
27 7. Using state-of-the-art technology, Genolab performs different types of
28

1 molecular testing for doctors, hospitals, and research institutions.

2 8. Doctors and hospitals routinely use and rely on Genolab’s test results
3
4 to make diagnoses and formulate patient treatment protocols.

5 9. In December 2020, Genolab was in the market to acquire one or more
6
7 gene sequencing instruments, which it uses to perform certain steps in its testing.

8 10. Gene sequencing instruments dramatically speed up the identification
9
10 process of pathogenic genetic variants, primarily because they evaluate large data
11 sets exponentially faster than human scientists.

12 11. For multiple years, Thermo Fisher has manufactured, marketed, sold,
13
14 and leased—whether directly or through subsidiaries—gene sequencing instruments
15 and software.

16 ***The Ion Torrent Genexus Integrated Sequencer (“Genexus Instrument”)***

17 12. Thermo Fisher describes the Genexus Instrument as “the first turnkey
18
19 next-generation sequencing (NGS) solution that automates the specimen-to-report
20 workflow and can deliver results in a single day.”¹

21 13. Intrigued at the prospect of streamlining and improving its sequencing
22
23 operations, Genolab began discussions and negotiations with Thermo Fisher for the
24 lease of a Genexus Instrument.

25
26
27

¹ <https://www.thermofisher.com/order/catalog/product/A45727>.

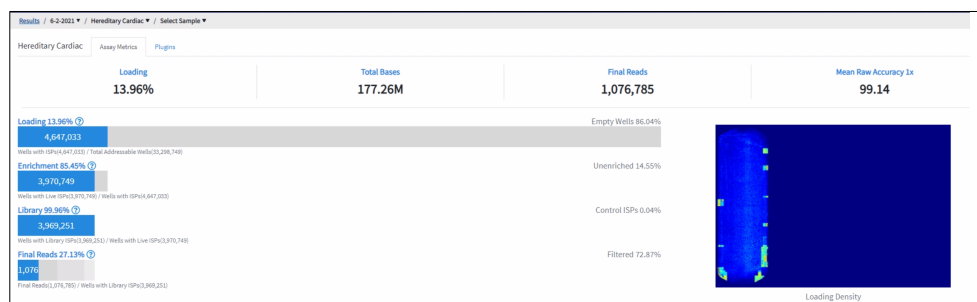
1 14. Thermo Fisher represented to Genolab that the Genexus Instrument was
2 fully capable of both reliably sequencing data and interpreting the data it produces.
3

4 15. On December 24, 2020, based on the representations about the quality,
5 characteristics, and performance of the Genexus Instrument, Genolab entered into a
6 lease agreement with TFFS, Lease No. x-6407 (the “Genexus Lease”), under which
7 Genolab agreed to lease a Genexus Instrument for 36 months at a rate of \$7,181.10
8 per month. Genolab also made a down payment of \$30,000.00.
9

10 16. As part of the Genexus Lease, Genolab purchased IQ/OQ/IPV² services
11 for the Genexus Instrument to verify the instrument’s ability to meet manufacturer
12 design specifications for performance.
13

14 17. On May 3, 2021, the parties signed an addendum to the Genexus Lease,
15 which reduced the monthly rate after the first month to \$6,273.49.
16

17 18. During instrument installation, the IQ/OQ was not completed, and the
18 result was catastrophic. See **Image 1**, below.
19



20
21
22
23
24
25 *Image 1*

26 ² IQ = Installation Qualification; OQ = Operational Qualification; IPV = Instrument
27 Performance Verification.
28

1 19. Image 1 shows the results from the first run of the Genexus Instrument
2 on June 2, 2021.

3
4 20. The amount of reads on this run was unacceptable according to Thermo
5 Fisher’s manufacturer instructions and did not pass quality control.

6
7 21. The Genexus Instrument also displayed an unknown and unidentified
8 camera and/or sensor issue, where it would request reagents be put in/taken out in a
9 random order—as opposed to systematically—and also would misidentify reagents
10 as used and/or expired when they were not.

11
12 22. A field service engineer (“FSE”) began troubleshooting, and a control
13 run was completed on June 3, 2021. *See Image 2*, below.

14

6-22-2021	HCPv2	16	Completed	2021-06-22 15:03	2021-06-23 12:48	Upload to IR Audit CSA
06-02-2021ControlRun	Training Assay - VS	4	Run Aborted	1234	2021-06-21 13:40	Audit Assign PCR Plate
ControlRun06102021	Training Assay - VS	8	Completed	2021-06-10 16:01	2021-06-11 06:43	Upload to IR Audit CSA
Test_733	Training Assay - VS	8	Library Preparation Aborted	2021-06-10 14:53	2021-06-10 14:56	Audit CSA Assign PCR Plate
Reanalysis_Run_6-2-2021 (Reanalysis)	Hereditary Cardiac	16	Completed	2021-06-02 17:45	2021-06-04 05:45	Upload to IR Audit CSA
06-03-2021ControlRun2	Training Assay - VS	4	Completed	2021-06-03 14:26	2021-06-04 02:27	Upload to IR Audit CSA
6-2-2021	Hereditary Cardiac	16	Stalled	2021-06-02 17:45	2021-06-03 14:04	Audit Assign PCR Plate

15
16
17
18 *Image 2*

19 23. However, once the control run was completed, it was determined that
20 the Genexus Instrument needed parts for the sensor.

21
22 24. On June 10, 2021, a Thermo Fisher FSE returned to Genolab after the
23 parts were received, and a test run was commenced. This test run failed, resulting in
24 the Genexus Instrument aborting it. *See id.*

25
26 25. A few hours later, another control run was commenced and completed.

27
28 26. On June 15, 2021, Thermo Fisher emailed Genolab, stating: “We still

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