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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

and belief, as follows:

PARTIES

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

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

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

JURISDICTION AND VENUE

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

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

FACTS

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

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

molecular testing for doctors, hospitals, and research institutions.

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

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

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

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

The Ion Torrent Genexus Integrated Sequencer ("Genexus Instrument")

12. Thermo Fisher describes the Genexus Instrument as "the first turnkey next-generation sequencing (NGS) solution that automates the specimen-to-report workflow and can deliver results in a single day."[1]

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

[1] https://www.thermofisher.com/order/catalog/product/A45727.

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

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

16. As part of the Genexus Lease, Genolab purchased IQ/OQ/IPV[2] services for the Genexus Instrument to verify the instrument's ability to meet manufacturer design specifications for performance.

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

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

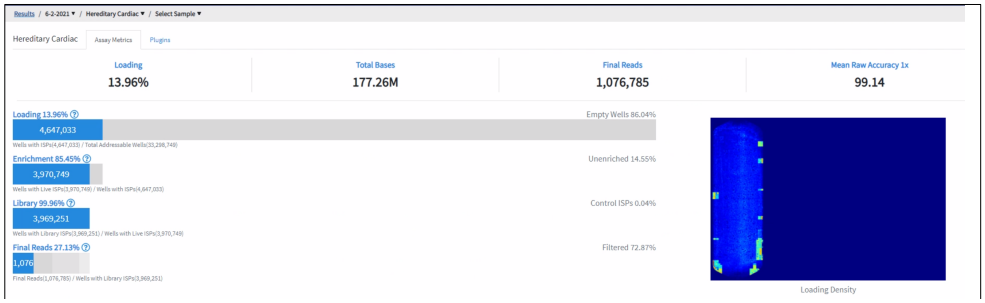


Image 1

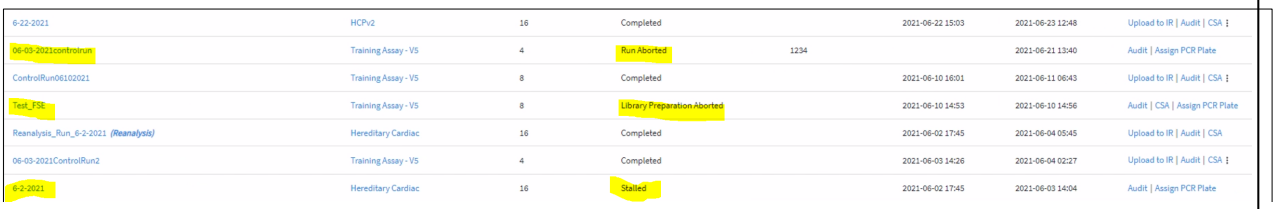
[2] IQ = Installation Qualification; OQ = Operational Qualification; IPV = Instrument Performance Verification.

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

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

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

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



6-22-2021	HCPv2	16	Completed		2021-06-22 15:03	2021-06-23 12:48	Upload to IR | Audit | CSA
06-03-2021controlrun	Training Assay - V5	4	Run Aborted	1234		2021-06-21 13:40	Audit | Assign PCR Plate
ControlRun06102021	Training Assay - V5	8	Completed		2021-06-10 16:01	2021-06-11 06:43	Upload to IR | Audit | CSA
Test_FSE	Training Assay - V5	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 - V5	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

Image 2

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

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

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

26. On June 15, 2021, Thermo Fisher emailed Genolab, stating: "We still

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