John W. Leardi
Frank X. Wukovits
BUTTACI LEARDI & WERNER LLC
212 Carnegie Center, Suite 202
Princeton, New Jersey 08540
609-799-5150
609-799-5180 FAX
Attorneys for Plaintiff
Gene Tox Worldwide LLC

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

GENE TOX WORLDWIDE, LLC, *Plaintiff,* - v. - THERMO FISHER SCIENTIFIC, INC., *Defendant.*	Case No. 21-CV-2854 **COMPLAINT and JURY DEMAND**

Plaintiff Gene Tox Worldwide, LLC d/b/a/ TruGenX ("TGX"), by way of Complaint against Defendant Thermo Fisher Scientific, Inc. ("TFS"), hereby alleges upon personal knowledge as to itself and its own acts, and upon information and belief as to all other matters, based upon, *inter alia*, the investigation made by and through its attorneys, as follows:

PARTIES

1. TGX is a molecular laboratory and offers real-time polymerase chain reaction ("RT-PCR") testing services, including SARS-CoV-2 ("COVID-19") testing, with a principal place of business at 136 Ridge Road, Lyndhurst, New Jersey 07071. TGX is accredited by the College of American Pathologists ("CAP"); CLIA certified by the Centers for Medicare and Medicaid Services ("CMS") in conjunction with the Food and Drug Administration ("FDA") and

Centers for Disease Control and Prevention ("CDC"); licensed by the New Jersey Department of Health ("NJDOH"); and licensed by the New York State Department of Health ("NYSDOH"). TGX's CAP accreditation, CLIA certificate issued by CMS in conjunction with the FDA and CDC, and licenses issued by both the NJDOH and NYSDOH represents that TGX continues to meet critical requirements, including but not limited to creating and implementing policies and procedures, as well as maintaining laboratory equipment.

2. TFS is an American manufacturer and supplier of laboratory instruments, reagents, consumables, software, and supplies, with its headquarters located at 81 Wyman Street, Waltham, Massachusetts 02451. TFS markets and sells such products in conjunction with various its subsidiaries and brands, including but not limited to Life Technologies Corporation ("LTC") and Applied Biosystems ("AB"). Among other products, TFS sells various COVID-19 testing instruments, test kits, reagents, and consumables, including but not limited to the AB 7500 Fast Dx Real-Time PCR Instrument ("7500 FDx RT-PCR") and TaqPath COVID-19 Combo Kit.

JURISDICTION AND VENUE

3. This Court has original jurisdiction over TGX's claims pursuant to 28 U.S.C. § 1332 because TGX and TFS are citizens of different states and the matter in controversy exceeds the sum of $75,000.00, exclusive of interest and costs.

4. This Court has personal jurisdiction over TFS because TFS is a resident of New Jersey by virtue of its authorization to conduct business in the State of New Jersey, by and through both foreign and domestically incorporated entities, and its operation and maintenance of offices within the State of New Jersey. Further, TFS maintains continuous and substantial activities with the State of New Jersey, whereby TFS has purposefully availed itself of the privilege of conducting activities within the State of New Jersey, thus invoking the benefits and protections of its laws.

5. Venue is appropriate in this District under 28 U.S.C. § 1391(b)(2) because a substantial part of the events giving rise to the claims occurred in New Jersey, including but not limited to representations made by TFS to TGX, the receipt of TFS's products purchased by TGX from TFS, COVID-19 testing issues with respect to TFS's products, services, and customer service, and the events or omissions by TFS giving rise to the claims set forth herein.

6. Venue is also appropriate in this District under 28 U.S.C. § 1391(b)(3) because the Court has personal jurisdiction over TFS.

FACTS COMMON TO ALL COUNTS

A. COVID-19 TESTING INSTRUMENTS, SUPPLIES, PROCEDURES, AND WORKFLOW

7. At all relevant times, TFS marketed and sold various products and instruments for COVID-19 testing to TGX, including but not limited to the 7500 FDx RT-PCR and TaqPath COVID-19 Combo kit.

1. The 7500 FDx RT-PCR

8. The 7500 FDx RT-PCR, which utilizes Sequence Detection System ("SDS") Software, is a real-time nucleic acid amplification and five-color fluorescence detection system that measures nucleic acid signals from reverse transcribed ribonucleic acid ("RNA") and converts them to comparative quantitative readouts.

9. From start to finish, the workflow for testing COVID-19 following the Emergency Use Authorization ("EUA") with this instrument includes the following: (1) RNA extraction from patient samples; (2) performance of the 7500 FDx RT-PCR; (3) review of the quality control ("QC") results; and (4) analysis of data using the Applied Biosystems™ COVID-19 Interpretive Software ("Interpretive Software").

10. First, samples are collected from patients. RNA is a critical component of the viral structure of COVID-19. COVID-19 RNA is generally detectable in nasopharyngeal swab,

nasopharyngeal aspirate, and bronchoalveolar lavage ("BAL") samples during the acute phase of infection.

11. Once collected and submitted to the laboratory, the 7500 FDx RT-PCR uses a variety of controls during the testing phase to reduce the risk of detecting other coronaviruses and accurately identify the presence of three specific coronavirus genes: ORF-1ab, N gene, and S gene. Specifically, the 7500 FDx RT-PCR uses a positive test control, MS2 phage control ("MS2"), and negative test control to accurately produce patient test results. Positive control is used to monitor RT-PCR reaction setup and reagent integrity. MS2 is used to monitor RNA extraction. Negative control is used to monitor cross-examination during RNA extraction and reaction setup. Together, these controls—commonly referred to as "reagents"—enable the 7500 FDx RT-PCR to accurately produce testing results on patients' samples.

12. As per TFS's Instructions for use to prep RT-PCR reactions using TaqPath COVID-19 Combo kit, patient samples and controls are pipetted into MicroAmp™ Fast Optical 96-well reaction plates ("reaction plates" or "plates"), which require the use of MicroAmp™ Optical adhesive film ("optical adhesive film"), which is a pressure activated seal. The reaction plate is used in this process to have one positive control, one negative control and 94 patient samples.

13. The proper workflow with respect to the use of optical adhesive film is as follows. First, laboratory personnel must place the reaction plate on a cold block. Then, laboratory personnel would add the master mix reagents and then pipette the samples into the sample wells. Thereafter, laboratory personnel must seal the plates using optical adhesive film on a splash-free base. Then the reaction plate is put through a process of vortexing and centrifugation. Finally, laboratory personnel must place the sealed reaction plate into the 7500 FDx RT-PCR. It is important to note that a product failure during any of these particular steps could lead to

contamination of both the samples and instrument, thereby leading to plate failure, inconclusive results, and/or invalid results.

14. To seal RT-PCR reaction plates with optical adhesive film, laboratory personnel must remove the backing of the adhesive film. Laboratory personnel must then align the optical adhesive film so as to cover all wells while placing on the plate, thereafter, laboratory personnel must apply pressure with the end of the applicator horizontally and vertically across all wells. Next, laboratory personnel must apply pressure with the flat edge of the applicator back and forth along the long edge of the plate. Laboratory personnel must then apply pressure with the flat edge of the applicator back and forth along the short edge (width) of the plate. Finally, the laboratory personnel must apply pressure with the end of the applicator around all outside edges of the plate using small back and forth motions to form a complete seal around the outside wells.

15. Once the 7500 FDx RT-PCR process or "runs" the plates, laboratory personnel must use the Interpretive Software to interpret the results. First, laboratory personnel must import the SDS files into the Interpretive Software. After importing the SDS files, the Interpretive Software analyzes the run data, performs Quality Check ("QC") analysis, and calculates the interpretive results for each sample and control. Thereafter, the Interpretative Software enables laboratory personnel to review the status and result for each sample and also export the results. Validation of the results is performed automatically by the Interpretive Software based on the performance of the positive and negative controls, whereby laboratory personnel are able to take the appropriate action depending on the results.

16. As per the instruction and procedural materials provided by TFS to TGX, the following table illustrates what corresponding action is required following a particular result as interpreted by the Interpretive Software:

ORF-1ab	N gene	S gene	MS2	Status	Result	Action
Negative	Negative	Negative	Negative	Invalid	N/A ("failed test")	Laboratory must repeat test. If the result remains invalid, laboratory must consider collecting a new specimen.
Negative	Negative	Negative	Positive	Valid	COVID-19 Not Detected	Laboratory must report result to healthcare provider, who should consider ordering testing for other viruses.
Only one SARS-CoV-2 target = POS			Positive or Negative	Valid	Inconclusive	Laboratory must repeat test. If the result remains inconclusive, additional confirmation testing should be conducted if clinically indicated.
Two or more SARS-CoV-2 targets = POS			Positive or Negative	Valid	COVID-19 Detected	Laboratory must report results to healthcare provider and appropriate public health authorities.

17. A positive result is indicative of the presence of COVID-19 RNA. If a sample returns as a positive result, TFS recommends that healthcare providers perform clinical correlation with patient history and other diagnostic information necessary to determine the patient's infection status. TFS also warns that positive results do not rule out bacterial infection or co-infection with other viruses as the agent detected may not be the definite cause of disease. It is also imperative to highlight that a negative result neither precludes COVID-19 nor serves as a sole basis for patient management decisions. Therefore, negative results must be combined with clinical observations, patient history, and epidemiological information.

18. Accordingly, laboratories within the United States and its territories, such as TGX, are required to report all accurate and valid results to both healthcare providers and the appropriate

public health authorities.

2. TaqPath COVID-19 Combo Kit

19. The COVID-19 Combo Kit includes two kits: TaqPath RT-PCR COVID-19 Kit ("RT-PCR Kit") and the TaqPath COVID-19 Control Kit ("Control Kit"). The RT-PCR Kit contains MS2 and assays targeting ORF-1ab, N gene, and S gene. The Control Kit contains COVID-19 control RNA (ORF-1ab, N gene, and S gene) and TaqPath COVID-19 control dilution buffer.

20. The COVID-19 Combo Kit is approved by the FDA for use in conjunction with the 7500 FDx RT-PCR. The Interpretive Software was allegedly designed to generate a report for each sample using the COVID-19 Combo Kit, whereby the Interpretative Software automatically interprets genetic analysis results from the COVID-19 Combo Kit and performs a QC check against all controls on the plate following instrument data analysis.

B. FDA ALERT TO CLINICAL LABORATORIES REGARDING TFS'S PRODUCTS

21. On or about August 17, 2020, the U.S. Food and Drug Administration ("FDA") issued a public alert to healthcare providers and laboratories with respect to "the risk of false results with Thermo Fisher Scientific TaqPath COVID-19 Combo Kit based on two issues related to the test kit and the associated Applied Biosystems COVID-19 Interpretive Software."

22. The first issue is related to inadequate vortexing and centrifugation of RT-PCR reaction plates, including the plates used by the 7500 FDx RT-PCR. According to the FDA, TFS's purported conclusion from internal investigations after receiving complaints from laboratories across the nation suggested that "inadequate vortexing or centrifugation can lead to false positive results." Accordingly, TFS allegedly updated its instructions to "reduce the risk of inaccurate results." The FDA emphasized, "the updated instructions related to vortexing and centrifugation are important for both laboratories performing testing according to the authorized instructions for

use and laboratories who are performing validated modifications outside of the authorization."

23. According to the FDA, the second issue with respect to TFS and its products requires laboratory staff to upgrade their software to decrease the potential need to retest and reduce the risk of failed tests, potential false negatives, and/or inconclusive results.

C. FDA DEVICE RECALL TAQPATH RT-PCR COVID-19 KIT WITH COVID-19 INTERPRETIVE SOFTWARE

24. On or about September 17, 2020, LTC—which was acquired by TFS in 2014—issued a recall with respect to the RT-PCR Kit and the Interpretive Software. LTC's products are loaded onto the TFS's system, whereby customers can order LTC's products through TFS. In relevant part, LTC's reasons for the recall include, "COVID-19 Interpretive Software issues that may cause: 1) the risk of invalid or inconclusive tests/false negative and potentially increasing the retesting burden on customers [and] 2) false positive results due to improper vortexing."

25. While LTC did not request the return of its products, LTC advised that the ongoing issues was "related to software and improper mixing/vortexing of the qPCR plate."

26. In the meantime, LTC recommended updating the Interpretive Software, completing training, and adhering to vortexing and COVID-19 testing recommendations by TFS.

27. To date, the recall status remains "Open," whereby the recall states, "LTC has initiated the recall and not all products have been corrected or removed. This record will be updated as the status changes."

D. TGX'S PURCHASES, USE, AND ISSUES RELATED TO TFS'S PRODUCTS

28. By early spring 2020, at the request of the government and community, TGX began to offer COVID-19 testing services in response to the pandemic.

29. TGX purchased its first 7500 FDx RT-PCR through TFS in April 2020. Accordingly, TGX underwent EUA workflow training for laboratory personnel's use of the 7500

FDx RT-PCR. Likewise, TGX installed and used Interpretive Software as directed. However, issues with respect to the 7500 FDx RT-PCR began to ensue shortly thereafter, whereby TGX produced a number of inconclusive results, invalid tests, and/or testing failures. The issues were inevitably traced by both TGX and TFS to alleged vortexing issues and Interpretive Software analysis.

30. On or about July 24, 2020, after continuous complaints, TFS Field Application Scientist Scott Gardner ("Mr. Gardner") notified laboratory personnel and members of TGX—including Chief Operating Officer Jimmy Kendrick ("Mr. Kendrick"), Laboratory Technician Ashleigh Showler ("Ms. Showler"), Laboratory Manager Maria Garcia ("Ms. Garcia"), and Vice President of Clinical Operations Christopher Williams ("Mr. Williams")—of widespread issues with respect to vortexing and the Interpretative Software, whereby Mr. Gardner recommended that TGX upgrade their versions of the Interpretive Software.

31. Despite these issues, which were never ultimately cured, TGX purchased various equipment and supplies from TFS over the course of the next several months, including but not limited to COVID-19 Combo Kits and three additional 7500 FDx RT-PCR instruments.

32. On or about September 4, 2020, Ms. Showler contacted Mr. Gardner via email that one of the 7500 FDx RT-PCRs experienced testing failures due to issues with the positive control. Ms. Showler attached data files generated by the Interpretive Software detailing the failures. In response, Mr. Gardner expressed that he believed that the positive control in the files were "degraded" without confirming the cause of the degradation.

33. On or about September 14, 2020, TGX contacted Mr. Gardner with respect to inconclusive results. Specifically, Mr. Williams informed Mr. Gardner that over the past few weeks, several patients' samples registered inconclusive results on consecutive tests. In fact, one

patient had submitted four different samples for testing, only to have each test conclude with an inconclusive result. TGX had expressed that referring providers were becoming increasingly uneasy with the increasing number of inconclusive results, inconclusive tests, and/or testing failures.

34. On or about September 26, 2020, Ms. Garcia submitted to Mr. Gardner data files generated by the Interpretive Software. The files detailed that there were no positive results corresponding with any of plates used during the then-recent testing. Upon information and belief, the plates either generated inconclusive results or testing failures since the Interpretive Software did not detect MS2 in the negative control. Ms. Garcia inquired as to whether TFS could provide the reasons for the failure, suggesting that there may be an issue with the MS2, 7500 FDx RT-PCRs, and/or Interpretive Software. In response, Mr. Gardner recommended Ms. Garcia contact TFS technical support. However, despite notifying TFS technical support, TFS neither ultimately revealed and explained the reason(s) for the inconclusive results and testing failures nor made attempts to resolve the issues in collaboration with TGX. In other words, TGX was left in the dark with these issues during this time.

35. On or about October 21, 2020, TFS Solutions Representative Wendy Ankener ("Ms. Ankener") informed Ms. Garcia that TFS was aware of the ongoing issues. To this end, Ms. Ankener expressed that she understood that TGX's COVID-19 testing had been interrupted and acknowledged that "MS2 amplification does not look good but needs to dive into data."

36. By November 2020, COVID-19 testing issues became progressively worse. Specifically, TGX continued to incur significant COVID-19 testing issues as the MS2 failed to amplify in the negative control when analyzed by the Interpretive Software, thereby causing the QC on the plates to fail. The issues became exponentially worse, as the MS2 failed to amplify in

any of the samples and causing most samples on the plate—including controls—to be invalid, thereby leading to more testing failures.

37. On or about November 6, 2020, Ms. Garcia notified Mr. Gardner and TFS technical support that SDS files were not uploading into the Interpretive Software. Specifically, the SDS files ran and were saved; however, the data was not uploading into the Interpretive Software. Unfortunately, Mr. Gardner's response disregarded the software issue as identified by Ms. Garcia, whereby Ms. Garcia expressed that Mr. Gardner's response "did not directly address this issue." To this end, Ms. Garcia expressed that TGX laboratory personnel were having significant "trouble uploading [COVID-19 SDS files] into the 7500 [] Interpretive Software." Mr. Gardner once again evaded the issue as well as Ms. Garcia's concerns by replying, "I feel it would be best to contact tech support at 800-955-6288 to see if they are able to resolve immediately. I have a feeling that something may have been corrupted with the. sdt template file, and that may have translated into the resulting .sds file." Once again, this issue was never resolved. Unfortunately, the issue continued without rectification or support. Without a solution from TFS, TGX's only alternative was to rerun the plates to get a .sds file that would upload.

38. On or about November 14, 2020, TGX notified Mr. Gardner and TFS technical support of further inconclusive results, invalid tests, and testing failures. In the ensuing days, approximately one hundred plates failed. TGX determined, which was later confirmed by TFS, that the testing failures were due to no amplification of MS2 in the negative control. The problem persisted as the MS2 was not amplifying in the samples. After two consecutive days of systematic plate failure, TFS Sales Specialist Dean Gilbert ("Mr. Gilbert") and Ms. Ankener instructed TGX to utilize the original stock-keeping units ("SKU") of Deep-Well Magnet Tip Combs ("tip combs"). In particular, TFS gave TGX these specific instructions as TFS had informed TGX that

other laboratories were experiencing similar issues when using alternative SKUs, which TGX had been forced to use due to TFS's supply shortage.

39. On the same day, Ms. Garcia also informed Mr. Gardner that the QCs continued to fail since the Interpretive Software did not detect MS2, thereby leading to an excessive number of invalid results. Ms. Garcia expressed to Mr. Gardner that TGX laboratory personnel ensured careful MS2 pipetting into the plate wells, and both thorough and proper vortexing was done. Ms. Garcia then requested assistance with how to troubleshoot these MS2 issues in order to move forward. In the meantime, these issues with MS2 continued to affect TGX's productivity.

40. To aid in the resolution of the ongoing issues, TGX provided TFS with data files evidencing the lack of MS2 amplification in the majority of the samples, whereby the Interpretive Software could not detect MS2 in either the samples or QC. In response to the issues, Mr. Gardner informed TFS sales and technical support personnel that "[i]t would be best for [TGX] to try a new tube of MS2 and see if that resolves the issue," thereby suggesting that the issue does not lie with TGX's workflow or procedures but the MS2 purchased from TFS. While Thermo was unable to resolve the ongoing issues, Mr. Gardner stated, "I feel it would be best to try a new tube of MS2, as I have a feeling the tube(s) that were used to generate these .sds files may be degraded."

41. On or about November 15, 2020, TFS Senior Account Executive Seth Josephson ("Mr. Josephson") attempted to downplay the existence of the issues with the COVID-19 testing despite the abundance of data files and testing documentation provided by multiple individuals at TGX to TFS as well as statements made by TFS personnel. Based on their conversations, Chief Executive Officer Charles Gentile ("Mr. Gentile") and Mr. Kendrick became increasingly concerned that the COVID-19 issues with TFS's products, instruments, and lack of support would persist, thereby affecting their testing capabilities, business relationships with referring providers,

and reporting obligations to both referring providers and public health authorities.

42. On or about November 16, 2020, Ms. Garcia submitted more data files to TFS, which evidenced continuous plate failure due to issues with the Interpretive Software, MS2, and positive control despite using fresh positive controls and following TFS's protocols.

43. On or about November 17, 2020, Ms. Garcia explained to TFS that TGX adhered to the workflow and instructions as provided by both the COVID-19 Combo Kit's Advanced Instructions for Use Manual and TFS's personnel. Specifically, TGX adhered to all instructions and provided by TFS to avoid inconclusive and/or invalid results, including but not limited to thoroughly vortexing; properly sealing plates; frequently changing tip combs when pipetting viscous solutions, such as master mix and magnetic beads; and ensuring volumes were consistent across the plates. For example, Ms. Garcia vividly explained to TFS that TGX would properly vortex the tube of COVID-19 RT-PCR multiplex assay prior to dispensing into the RT-PCR reaction mix, which consists of the multiplex assay, master mix, and water. Once TGX would make the reaction mix, TGX would then carefully make sure to pipette the reaction mix into each well. This mix was made fresh and the process was repeated each time accordingly, which TGX had done from the beginning.

44. Thereafter, TFS Technical Application Scientist Ekaette Mbong ("Ms. Mbong") informed Ms. Garcia that Mr. Gardner concluded that "this issue was resolved with a new tube of positive control."

45. In addition, TFS sent TGX two boxes of original SKU tip combs for purposes of replacing TFS's earlier shipment.

46. On or about November 23, 2020, Ms. Garcia submitted more data to TFS, depicting failed plates and testing information from the week prior. In particular, the data generated by the

Interpretive Software revealed—as Ms. Garcia carefully articulated—that each of these plates had an issue with TFS's MS2 and/or positive control. Ms. Garcia reiterated that every single step of the process was done the same way for each run, including steps involving storage, extraction, and vortexing. Ms. Garcia informed TFS that both the MS2 and positive control were kept in the appropriate freezers and at the appropriate temperatures; but nevertheless, the MS2 and positive control degraded quickly.

47. On or about November 24, 2020, neither TFS Technical Applications Scientist Megan Palm ("Ms. Palm") nor the TFS quality team "ha[d] anything concrete yet" with respect to TGX's persistent inconclusive and failures. Moreover, TGX continued to accrue software issues. In response, Mr. Gardner dismissed these issues and merely suggested TGX, "The simplest thing you can try is to restart your computer, and try the software again. If this does not work, you can try having your local IT resolve the situation."

48. On or about November 25, 2020, issues with reaction plates as well as inconclusive results, invalid tests, and/or testing failures continued as the Interpretive Software indicated that the MS2 failed to amplify in the controls or the samples. After informing Ms. Ankener, she confirmed that this could potentially be the MS2 and provided TGX with a shipment of MS2 replacements, which TGX began to use immediately.

49. On or about November 27, 2020, TFS Field Applications Scientist Geoffrey Jackson ("Mr. Jackson") visited TGX to review TGX's workflow. After conducting a close review of TGX's workflow and procedures, Mr. Jackson had informed TGX's laboratory personnel that TGX's laboratory personnel had been following the proper procedures with respect to the 7500 FDx RT-PCRs and Interpretive Software, whereby Mr. Jackson expressed that the issues with the 7500 FDx PCRs were not created by TGX's personnel, workflow, or procedures.

50. On or about December 1, 2020, Ms. Garcia informed Mr. Jackson that the 7500 FDx RT-PCRs were experiencing various issues with the Interpretive Software, whereby none of the 7500 FDx RT-PCR tests were properly registering with the Interpretive Software. TFS attributed the issues with the Interpretive Software to optical mixing issues but simultaneously could not explain why the Interpretive Software generated an "incomplete file."

51. By December 4, 2020, TFS had been made well aware of TGX's testing issues, particularly with the 7500 FDx RT-PCRs, Interpretive Software, reagents and consumables purchased through TFS. To this end, Field Service Engineer Mas'uud Washington ("Mr. Washington") sent Ms. Garcia a text asking, "Any more trouble with the software this week?" Unfortunately, TGX indeed continued to experience issues with the Interpretive Software and across the board.

52. On or about December 6, 2021, Ms. Garcia was informed by Mr. Jackson that TGX's testing issues may have been the result of the Interpretive Software and what Mr. Jackson referred to as the "waterfall effect," which could be *potentially* "resolved in the latest version of the [Interpretive Software]." However, TGX only received an email notifying TGX of a mandatory update for the latest version of the Interpretive Software on or about December 4, 2020—well after TGX began to experience significant COVID-19 testing issues. Specifically, Mr. Jackson suggested that the waterfall effect was occurring because the wells on the testing plates "would appear to be positive but these targets [were] not true amplification. In fact, none of the targets amplified in this well[,] not even MS2." Mr. Jackson explained that this issue would create the appearance of a waterfall on the results generated by the Interpretive Software, thereby leading to inconclusive results or testing failures.

53. On or about December 8, 2020, the reaction plates started to fail again, even after

TGX updated the Interpretive Software. In particular, the Interpretive Software failed to detect MS2 amplification in both the control and the samples. Mr. Jackson and Mr. Gardner were on-site at TGX for a total of four days troubleshooting and reviewing TGX's workflow; however, to no avail. To make matters worse, when unable to identify the cause of the issues, Mr. Gardner would typically attribute the issues related to vortexing and directed TGX to vortex the reagents for at least thirty (30) seconds. However, Mr. Jackson contradicted Mr. Gardner's instructions and warned TGX's laboratory personnel that vortexing more than twenty (20) seconds could degrade the reagents.

54. Regardless, TFS's personnel confirmed that TGX's workflow was in order but plates nevertheless continued to fail. Upon information and belief, the reagents—specifically the MS2—failed to register with the Interpretive Software, thereby causing inconclusive results, invalid test, and/or testing failures.

55. Upon information and belief, several other laboratories were experiencing similar issues, as suggested by Mr. Jackson. Similar to how he instructed other laboratories, Mr. Jackson instructed TGX to use two negative controls and two positive controls for the 7500 FDx RT-PCR plates, which would supposedly increase the chance of passing reaction plates and generating valid results. To this end, while there was a change in the EUA which allowed for the use of more than one control—which does not appear in the EUA revision list—it also does not provide for how the results of those QCs shall be interpreted.

56. Moreover, while Mr. Jackson instructed TGX to add two positive and two negative controls to a reaction plate, Interpretive Software only provides for two controls to a plate. Mr. Jackson would advise TGX to make the QC that passed for each control, "to assign it the control task" and leave the others as unknowns. This is antithetical to not only clinical laboratory practices

but also the EUA. In fact, around this time, Mr. Jackson proceeded to request Ms. Garcia data files evidencing inconclusive results, whereby Mr. Jackson would manually interpret the parameters of inconclusive results in lieu of the Interpretive Software; once again, this is yet another example of TFS's efforts and practices exceeding the EUA so that TFS may continue to sell and market its products, which failed to perform as specified, marketed, and represented by TFS.

57. On or about December 8, 2020, a teleconference took place between members of TGX and TFS. During this teleconference, TFS Senior Director Lori Emrick ("Ms. Emrick") and TFS Technical Sales Specialists Paula Miccinesi ("Ms. Miccinesi")—both of whom TGX was unable to reach for almost the entirety of TGX's COVID-19 testing issues—admitted TFS's negligence regarding the ongoing issues with respect to TFS's products and repeatedly apologized for the supply chain issues and lack of conducive customer support.

58. During this teleconference, both Ms. Emrick and Ms. Miccinesi attempted to explain why TFS's internal investigation was virtually non-existent or delayed, at best. At this point, they promised to contact TGX within a few short days regarding the conclusions of their internal investigation and a solution for the continuous invoices for reagents and testing supplies that continued to generate either inconclusive results or testing failures. TGX was also instructed not to use vast quantities of defective and/or warped supplies and reagents purchased from TFS. However, despite TFS's promises and representations, TGX was unable to subsequently reach Ms. Emrick or Ms. Miccinesi regarding the results of any internal investigation or solution with respect to the issues with TFS's defective products and accruing invoices, which is beyond insult to injury and indicative of TFS's intent to not only profit off of TGX without TGX receiving the benefit of its bargain but also TFS's intent to deceive and defraud TGX.

59. Meanwhile, replacements were often delayed, missing, incorrect, or undelivered

altogether. On the other hand, even when TGX received these replacements, they would inevitably lead to inconclusive results, invalid tests, and/or testing failures; and of course, these purported "replacements" came at additional costs to TGX.

60. On or about December 8, 2020, Mr. Gilbert informed TGX that he could come on-site at TGX and take the alternative tip combs from TGX. Mr. Gilbert had expressed to TGX:

> As [Ms. Ankener] pointed out several times last week[,] [TFS] accidentally sent 5 cases of the alternative tip combs to your facility and [Ms. Garcia] put them aside. Additionally, can I take the older lots of alternatives that you have on-site. We only want to have the non-alternative tip combs at your facility. We want to ensure that there is never an accident with someone mixing up a sleeve of them. Visually everything looks the same. I don't remember if the sleeves are labeled with the cat# which I dont think they are. If they are not labeled and there are any questionable sleeves please provide them to me. We just want to Eliminate that factor. The new standing order is set up so you will only receive the non-alternative cat #s for tip combs. Please let me know some windows that I can come in.

61. On or about December 9, 2020, TGX received a shipment of replacements and new testing supplies from TFS, including but not limited to multiplex master mix, viral/pathogen nucleic acid isolation kit, microplates, tip combs, clear adhesive film, reaction plates, and optical adhesive film.

62. On or about December 9, 2020, plates began to briefly pass again until Mr. Williams submitted data to TFS detailing inconclusive results, invalid tests, and/or testing failures. Mr. Gentile followed up and expressed that the testing failures would continue unless and until TFS produced its finding with respect to its purported internal investigation and identified the ultimate cause(s) for the testing failures. In the meantime, TGX continued to take inventory of the testing supplies and reagents they had purchased from TFS that TGX had no choice but to store or discard as per TFS's instructions.

63. On or about December 13, 2020, Mr. Jackson informed Ms. Garcia that TFS was "working on getting replacement reagents and plastics for everything in [TGX's] entire workflow."

64. On or about December 16, 2020, Ms. Garcia notified Mr. Gardner, Mr. Jackson, and TFS technical services personnel that a plate had failed, whereby the ORF-1ab gene was detected in one of the negatives; MS2 was not detected in either of the negative controls; and there was no detection of MS2 in the samples. After reviewing the data submitted by TGX, TFS confirmed (1) N gene had amplified in two wells; (2) N gene had not amplified in the rest of samples; and (3) the MS2 control was weakly amplified in the negative control and a few samples.

65. On or about December 17, 2020, Mr. Gentile provided TFS with a full failed plate report and a list of all inconclusive results in the past six weeks.

66. On or about December 18, 2020, Mr. Washington told Ms. Garcia that Ms. Ankener had "informed him of failures you all had for the past few weeks" involving the 7500 FDx RT-PCRs. However, Mr. Washington was unable to provide any insight or answers with respect to these failures.

67. On or about December 19, 2020, Mr. Gentile expressed that after reviewing TGX's inventory that TGX was in possession of vast quantities of MS2 and reagents that members of TFS told him was unusable, whereby TFS specifically instructed TGX not to use these supplies for COVID-19 testing. Mr. Gentile discussed with Mr. Gilbert and Ms. Ankener the issue of credit for the unusable inventory. However, TFS continued to charge TGX for not only defective testing supplies and reagents but also the replacements.

68. On or about December 24, 2020, Mr. Jackson told Ms. Garcia, "I am working with our internal team to get your lab reimbursed. I may need one final experiment (same samples with new reagent and old reagent to further make the case)." However, Mr. Jackson failed to acknowledge the abundance of data files and reports submitted to TFS over the past several months, all of which evidenced the issues and detailing the reagents used.

69. On or about December 28, 2020, the plates began to fail again as a result of QC failure. However, TGX discovered that even if the QCs passed on a reaction plate, the N gene was in the samples, thereby contributing to excessive inconclusive results and false positives. Ms. Garcia then provided Mr. Jackson with data files evidencing such. In response, Mr. Jackson acknowledged that the inconclusive results were due to the reagents, amplification, and possible contamination issues rather than TGX's workflow.

70. On or about December 29, 2020, Mr. Jackson confirmed with Ms. Garcia via text message that "the inconclusive [results] are due to the amplification of one target." Nevertheless, despite the inconclusive results, Mr. Jackson continued to request data depicting the inconclusive results from Ms. Garcia, whereby Mr. Jackson attempted to manually interpret—in lieu of the Interpretive Software—which inconclusive results were supposedly positive or negative results.

71. On or about December 30, 2020, Ms. Garcia informed TFS that testing failures persisted due to N gene amplification. As for the plates that did not experience failure, they nevertheless produced a high number of inconclusive sample results. Ms. Garcia requested for a TFS engineer to come on-site to help identify and resolve the issue; however, to no avail.

72. On or about January 1, 2021, Mr. Kendrick informed Mr. Jackson that because COVID-19 testing issues continued, including but not limited to plate failures, lack of resolution by TFS, unethical and inappropriate manual interpretations by Mr. Jackson in place of the Interpretive Software, and the financial burden incurred, TGX had no choice but to stop all COVID-19 testing until the issues could be resolved once and for all. To aid in the final resolution of the issues, Ms. Garcia sent the then-most recent data files to Mr. Jackson, who later informed Ms. Garcia via text that at least "[o]ne of the plates needs to be re-run because of optical mixing issues that are affecting the whole plate." Despite the ongoing issues, Mr. Jackson continued to

commend TGX's workflow and even told TGX's staff that their "work ethic is unprecedented." TGX was told use the newest lot numbers.

73. Upon information and belief, TGX had also determined based on the recent data that TFS had sold TGX vast quantities of faulty plate seals, which (1) produced a high number of inconclusive results; (2) caused reaction plates to fail; and (3) delayed testing procedures. Among other evidence, TGX was led to this conclusion because even if the Interpretive Software had worked properly—despite previous issues involving or caused by the Interpretive Software—the Interpretive Software was incapable of producing accurate results since faulty plate seals would contribute to analysis issues, such as contamination.

74. Specifically, in an email to Ms. Garcia, Ms. Palm mentioned other laboratories had similar issues with TFS's optical seals and requested the lot numbers—identification numbers assigned to a particular quantity or lot—for the optical seals. Similarly, Mr. Gilbert called Mr. Kendrick and also asked for the TFS lot numbers for the TFS optical seals in TGX's possession, whereby TGX provided TFS with the lot numbers. However, after providing TFS with the lot numbers for the optical seals, TFS never followed up or informed TGX that those lot numbers were indeed associated with the optical seals that were defective or gave other laboratories issues.

75. On or about January 3, 2021, TGX presented this determination to TFS, whereby Mr. Jackson then accused TGX of misusing TFS's products, including but not limited to the plate seals. In response, Mr. Kendrick vehemently disputed Mr. Jackson's accusations and stated:

> You have been on sight with our staff, you have reviewed our workflow, and you have said that we follow protocol to the letter. You have also been in the PCR prep room while we are sealing plates for the Instruments and didn't point this out as a potential problem. I also followed up with [Ms. Garia], and she is 100% confident that this does not occur, and listed several reasons why it couldn't. 1. The adhesive seals and the Optical seals are in different type packages. One is in a bag, the other is in a box. 2. The adhesive seals and the Optical seals have a totally different thickness and feel. 3. The adhesive seals are sticky and the Optical seals have to be

> pressure sealed to the plate. This is a very different process and could not be mixed up. 4.The Optical seals have the tabs on the ends that have to be pulled off before inserting into the instrument. This would be noticed by any of our techs if they had not used the correct seal. Our technicians have all been working with the Thermo Covid EUA method for months and are very seasoned in the protocol for Covid sample prep. I don't believe this has been an issue for us. Thank you for your continued support. We appreciate all that you do for us here at TruGenX.

76. In response, Mr. Jackson retracted his accusation and indicated that he "completely agree[d]," "spoke with [Ms. Garcia] earlier to confirm," and claimed TFS would "continue to do everything in [its] power to resolve this once and for all."

77. Upon information and belief, TGX's conclusion that contamination with respect to the faulty optical adhesive film and the contamination of the 7500 FDx RT-PCRs was at least a contributing factor to inconclusive results, invalid tests, and/or testing failures was further corroborated by interactions with other TFS personnel, including but not limited to TFS Field Service Engineer Kevin Moulton ("Mr. Moulton").

78. On or about January 3, 2020, Mr. Moulton finally came on-site to diagnose the issues with the 7500 FDx RT-PCR. In his field service report, Mr. Moulton listed "[c]ontamination" under the heading 'PROBLEM DESCRIPTION' and wrote in relevant part, "[TGX] reported of high background, the sample blocks were cleaned several times for 2 of 4 instruments, however the issue still remained. The sample block was eventually replaced on 3 [the 7500 FDx RT-PCRs]."

79. On or about January 3, 2020, Ms. Miccinesi called Mr. Gentile and apologized for the ongoing issues, whereby she admitted that TFS's personnel had been negligent with respect to not only TFS's products but also TFS's personnel's response and lack of rectification of the issues, whereby Mr. Gentile expressed that TGX has been double-charged for defective products and consequently begun to suffer cash flow issues.

80. Upon information and belief, TFS made fraudulent and/or negligent misrepresentations with TGX with respect to specifications, production, performance, and quality of TFS's products on several occasions—before, during, and after TGX purchased COVID-19 testing products and supplies from TFS.

81. On or about January 5, 2020, Mr. Gentile spoke with Ms. Miccinesi over the phone asked about which products are outsourced and which are manufactured. When Mr. Gentile asked Ms. Miccinesi if TFS manufactured the MS2, Ms. Miccinesi claimed that TFS did. However, upon information and belief, this is false, as TGX has reliable sources who have indicated that TFS outsources the MS2 because—in the laboratory supply industry—MS2 is a high volume, low margin commodity, whereby TFS focuses on higher profit margin reagents in-house and resells the outsourced MS2 at an increased price. Similarly, when asked if TGX was purchasing alternative plastics, tip combs or optical seals, Ms. Miccinesi claimed she could not confirm. When Mr. Gentile asked Ms. Miccinesi whether Ms. Emrick would be able to provide such information, Ms. Miccinesi replied that Ms. Emrick would be unable to provide such information as well. Nevertheless, Ms. Miccinesi continued to apologize for TFS's negligence during the entirety of TGX's COVID-19 testing issues. Ms. Miccinesi also promised Mr. Gentile a letter that TGX could provide referring providers in an effort to explain the ongoing testing issues occurring at TGX with respect to TFS's products and supplies; however, this is yet another unfulfilled promised made by TFS to TGX.

82. On or about January 6, 2021, testing had gotten exponentially worse. TGX expressed to TFS that laboratory personnel were not comfortable releasing results due to the high number of positive and inconclusive results, which were increasingly being manually interpreted by Mr. Jackson. Consequently, TGX could not perform testing on over 1000 specimens TGX

received between December 29, 2020 and January 5, 2021, and could not report over 1600 specimens that had been tested but not able to report due to questionable results.

83. On or about January 8, 2021, TGX finally received the letter that was promised to them by Ms. Emrick and Ms. Miccinesi on or about December 8, 2020. This letter, authored by TFS Senior Quality and Compliance Manager Johnny Lim ("Mr. Lim"), claimed that TFS was unable to "identify and confirm the root cause" of the reported issues. Moreover, Mr. Lim then brazenly shifted the cause of the issues onto TGX.

84. In brief, Lim's letter acknowledged TGX's ongoing issues with TFS's products and claimed that the products at issue were still under review. Explicitly, the letter stated, "these investigations are still active; however, to date [TFS] does not believe that the reported problems were the result of any [TFS] product performance issues."

85. Boldly, Mr. Lim's letter (1) claimed TFS had been purportedly unable "identify and confirm the root cause"; (2) alleged that the "investigations are still active"; (3) contradicted TFS's on-site Field Service Engineers' and Field Application Scientists' conclusions communicated to TGX that the issues were not the result of TGX's operations and workflow; and (4) blatantly ignored that TGX had been forced to suspend all COVID-19 testing since TGX had been unable to produce readily accurate and conclusive testing results using instruments and products purchased through and serviced by TFS. All the meanwhile, Mr. Lim's letter concealed that the ongoing issues at TGX were neither isolated nor unique, whereby laboratories across the nation had been experiencing the same issues with the 7500 FDx RT-PCRs, Interpretive Software, reagents, reaction plates, and supplies; all of which, were purchased by TGX through TFS.

86. In all, TGX has incurred significant financial, operational, professional, and reputational hardship due to TFS's products and services, which are at the heart of the August

FDA 2020 public alert, September 2020 FDA manufacturer recall, and purported January 2021 TFS internal investigation; all of which remain open, active, and ongoing. Moreover, despite submitting data files to TFS as per TFS's requests, updating the Interpretive Software as per TFS's instructions, completing training as mandated by TFS, vortexing as per TFS's manuals and updated protocols, and adhering to the proper workflow as per TFS's materials and guidance; TGX has incurred significant costs as it relates to TFS's laboratory instruments, supplies, and reagents, which meet neither TFS's specifications nor TGX's expectations as set and mislead by TFS's persistent fraudulent and negligent misrepresentations, which have severely impacted TGX's testing capabilities, business relationships with referring providers, and ability to report valid results to the both referring providers and the appropriate public health authorities.

COUNT I
BREACH OF CONTRACT

87. TGX hereby restates and re-alleges each of the allegations contained in the foregoing paragraphs as is set forth fully therein.

88. Pursuant to COVID-19 testing, TFS offered TGX a multitude of products, including but not limited to the 7500 FDx RT-PCR, Combo Kit, reagents, reaction plates, and various supplies necessary for COVID-19 testing.

89. In exchange for TFS's products, TGX paid TFS millions of dollars in exchange for TFS's products, including but not limited to the 7500 FDx RT-PCR, Combo Kit, reagents, reaction plates, and various supplies necessary for COVID-19 testing.

90. However, TFS breached its obligations under their arrangement, whereby TFS's products were defective and/or failed to produce the desired result as intended, advertised, and represented to TGX.

91. As a direct and proximate result of TFS's past and continued breach of contract,

TGX has suffered and continues to suffer substantial losses that have arisen naturally according to the usual course of things from the breaches of contract, or such as was fairly and reasonably be contemplated by the parties to the contact at the time it was made a probable result of the breach.

COUNT II
BREACH OF EXPRESS WARRANTY

92. The foregoing allegations are re-alleged and incorporated by reference as if fully set forth herein.

93. TFS is liable to TGX for failure to provide a design and product that meets a standard of performance promised by TFS to TGX, whereby TFS warranted that each product it sold to TGX would meet its specification and would be free of defect in materials and workmanship, when subjected to normal, proper, and intended usage by TGX's properly trained personnel.

94. As per the Terms and Conditions of Sale, TFS warranted to TGX that its instruments—including but not limited to the 7500 FDx RT-PCR—would be free of defects in materials and workmanship, when subjected to normal, proper, and intended usage by properly trained personnel, for twelve (12) months from the date TFS shipped the instrument to TGX, or in the case of instruments that require installation by TFS personnel, twelve (12) months from installation.

95. As per of the Terms and Conditions of Sale, TFS also warranted that spare parts purchased from TFS and that TFS would install or are installed by a company TFS has certified as an authorized installer, would be free of defects in materials and workmanship for three (3) months from the date TFS delivered them, or, if longer, the original warranty period of the instrument in which the part is installed.

96. As per the various and numerous representations made by TFS's personnel,

representatives, and agents, TFS warranted that its products would meet their specifications and adhere to its performances as intended for COVID-19 testing.

97. At all relevant times, TGX used TFS's products in a manner that TFS reasonably could have foreseen. Further, TGX used TFS's products in an appropriate manner, whereby TGX adhered to the proper and necessary workflow as required and explicitly described by TFS's written materials, personnel, representatives, and agents.

98. Nevertheless, TFS violated its various express warranties, whereby TFS's products—including but not limited to the 7500 FDx RT-PCRs, Combo Kits, reagents, reaction plates, and various supplies necessary for COVID-19 testing—failed to meet its specifications and create its intended result as represented in both the Terms and Conditions of Sale as well as the representations made by TFS's personnel, representatives, and agents—despite TGX adherence to the proper and necessary workflow as required and explicitly described by TFS's written materials, personnel, representatives, and agents.

99. As a direct and proximate result of TFS's past and continued breach of warranties, TGX has suffered and continues to suffer substantial losses that have arisen naturally according to the usual course of things from the breaches of warranties.

COUNT III
FRAUD

100. The foregoing allegations are re-alleged and incorporated by reference as if fully set forth herein.

101. As alleged in vivid detail herein, TGX has articulated with particularity the numerous circumstances and instances constituting fraud, whereby TGX has not only explicitly identified the time, dates, persons, methods, and channels through which TFS perpetuated their fraudulent practices, but TGX has also advanced facts illustrating TFS's misrepresentations, intent

to deceive TGX, and the consequences of TFS's purposeful misrepresentations, whereby TFS greatly profited from TGX's demise.

102. TFS has exhibited deceptive and fraudulent practices, executing a scheme involving the sale of defective products and subsequent promises of valid replacements, corrective actions, and credit for faulty and defective products by no fault of TGX. This scheme set off a frenzy of malicious misrepresentations and sales to TGX, who has incurred significant and substantial losses because of TFS's misrepresentations, defective products, and promises of replacement and/or credit.

103. Importantly, TFS knew or has reason to know—by way of its scheme or, at the very least, the open, active, and ongoing August FDA 2020 public alert, September 2020 FDA manufacturer recall, and purported January 2021 TFS internal investigation—that its representations to TGX were false; the products it sold to TFS were defective; replacements would not resolve the ongoing COVID-19 testing issues by no fault of TGX; and COVID-19 testing issues would never be cured by way of replacements and credit to TGX.

104. In an effort to induce TGX to purchase and continue purchasing COVID-19 testing instruments, products, and supplies from and through TFS, Defendant TFS made fraudulent misrepresentations to TGX through TFS's agents about their products with knowledge of their falsities, for the purpose of inducing TGX to act on TFS's misrepresentations, whereby TGX reasonably relied on TFS's misrepresentations as true and acted upon them to TGX's detriment.

105. Conclusively, TFS made false representations of material fact with knowledge of its falsity for the purpose of inducing TGX to act thereon, and TGX reasonably relied upon TFS's misrepresentations as true and acted upon them, thereby resulting in damage to TGX.

COUNT IV
NEGLIGENT MISPRESENTATION

106. The foregoing allegations are re-alleged and incorporated by reference as if fully set forth herein.

107. Through its agents, Defendant TFS—in the course of its business and transactions with TGX who at all times maintained a pecuniary interest—supplied false information for TGX's purchases, consideration, and guidance in the above referenced and explicitly detailed transactions without exercising reasonable care or competence in obtaining or communicating the information, whereby TGX justifiably relied on the information and consequently suffered significant pecuniary loss caused by their justifiable reliance upon the information provided by TFS.

108. Specifically, TGX detrimentally relied on TFS's representations with respect to (1) the functionality, specifications, and usability of TFS's products, including but not limited to the 7500, Interpretive Software, COVID-19 Combo Kits, and Optical seals, as communicated to TGX by agents of TFS via teleconferences, in-person conversations, text messages, emails, published catalogs, and associated marketing materials; (2) the allegedly necessary replacements for TFS's products; (3) earning credit with respect to TGX's unusable inventory; and (4) purported solutions to cure TGX's COVID-19 testing issues related to TFS's products.

109. TGX was at the mercy of TFS, who not only negligently promised to rectify the issues with its products but also attempted to shift the blame for any issues related to the products onto TGX, despite the open, active, and ongoing August FDA 2020 public alert, September 2020 FDA manufacturer recall, and purported January 2021 TFS internal investigation.

110. Conclusively, TFS negligently made representations of material fact, whereby TGX reasonably relied upon TFS's misrepresentations as true and acted upon them, thereby resulting in damage to TFS.

PRAYER FOR RELIEF

111. The foregoing allegations are re-alleged and incorporated by reference as if fully set forth herein.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment against Defendant for damages not less than one-million five-hundred thousand dollars ($1,500,000.00), including punitive damages for Defendant's malicious, fraudulent, negligent, and oppressive conduct that reflects a conscious and purposeful disregard of Plaintiff's rights, together with interest, costs of suit, attorneys' fees, and any other relief the Court deems as just and proper.

JURY DEMAND

Plaintiff hereby demands trial by jury as to all issues so triable.

CERTIFICATION PURSUANT TO LOCAL CIVIL RULES 11.2 AND 40.1

I hereby certify that, to the best of my knowledge, the matter in controversy is not the subject of any other pending or anticipated litigation in any court or arbitration proceeding, nor are there any non-parties known to Plaintiffs that should be joined to this action. In addition, I recognize a continuing obligation during this litigation to file and to serve on all other parties and with the Court an amended certification if there is a change in the facts stated in this original certification.

CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 201.1

I hereby certify that the above-captioned matter is not subject to compulsory arbitration in that the Plaintiffs seek damages exceeding $150.,000, exclusive of interest and costs.

Dated: February 18, 2021

Respectfully submitted,

/s/ John W. Leardi

John W. Leardi
Frank X. Wukovits
BUTTACI LEARDI & WERNER LLC
212 Carnegie Center, Suite 202
Princeton, New Jersey 08540
609-799-5150
609-799-5180 FAX
Attorneys for Plaintiff
Gene Tox Worldwide LLC