Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 10D2161865	**(X3) Date Survey Completed** 11/19/2020
Name of Provider or Supplier Stone Clinical Laboratories Of Fl Llc	**Street Address, City, State** 315 Serenoa Rd, Santa Rosa Beach, FL	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	**Summary Statement of Deficiencies**
D0000	An unannounced complaint survey #2020016404 was conducted on 11/17/20-11/19/20 at Stone Clinical Laboratories of Florida LLC. The laboratory was not in compliance with 42 CFR Part 493, requirements for Clinical Laboratories. Based on the survey findings an Immediate Jeopardy situation was identified and the laboratory was notified at 3:51 pm on 11/19/20. 1. The laboratory failed to follow their own written policy for specimen receipt and handling for 3 of 3 days specimens were received from outside clients for COVID-19 testing (10/02/2020, 10/04/2020, 10/06/2020). Refer to D5311, I. 2. The laboratory failed to ensure specimens for COVID-19 testing had not exceeded their stability for 9 of 10 Runmei swabs and 1 of 10 Beaver swabs (sampling from 10/09/2020 and 10/10/2020). Refer to D5311, II. 3. The laboratory failed to verify shipping/transport conditions for specimens (from outside clients) maintained temperature according to manufacturer's instructions for 1,254 of 1,254 specimens observed on 11/17/2020 and 9 of 9 specimens from a sampling received 10/09/2020. Refer to D5311, III. 4. The laboratory's preanalytical policies and procedures were inconsistent with manufacturer's instructions for Beaver swabs. Refer to D5311, IV. The following Conditions were not met: D5300 - 493.1240 - Preanalytic Systems D5400 - 493.1250 - Analytic Systems D6076 - 493.1441 - Laboratory Director D6168 - 493.1487 - Testing Personnel D6108 - 493.1447 - Laboratory Technical Supervisor
D3027	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(1) Test requisitions and authorizations. Retain records of test requisitions and test authorizations, including the patient's chart or medical record if used as the test requisition or authorization, for at least 2 years. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy, final test reports, and in interview with staff, the laboratory failed to retain 2 of 13 test requisitions for COVID-19 testing

	(specimens received 10/05/2020 and 10/07/2020). Findings included: 1. Review of the laboratory's policy "Specimen Acceptance and Rejections" (SOP #: GENFL-7) stated, "III. Policy A. Requisition Acceptance 1. All specimens must be accompanied by a requisition form." 2. In a sampling of final test reports of COVID-19, the laboratory did not have the test requisitions for the following: Patient #20134491 - collected 9/29 /2020 at 10:53 am, received 10/05/2020, result reported 10/06/2020 at 10:36 am. Patient #11018216 - collected 9/29/2020 at 8:00 am, received 10/07/2020, result reported 10/06/2020 at 10:36 am. 3. During an interview on 11/18/2020 at 12:19 pm, the Team Lead of Accessioning was unable to provide the requisitions; he stated they might be in New Orleans, LA. He stated they may have been reviewed there because of how busy they were during that time.
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: Based on direct observation, review of laboratory's policy, patient test requisitions, instrument data, patient final test reports, and in interview with staff, the laboratory failed to ensure positive identification of a mislabeled patient specimen for COVID-19 testing (11/16/2020). Findings included: 1. During the tour of the accessioning area on 11/17/2020 at 11:12 am, patient swabs that had been analyzed for COVID-19 testing on 11/16/2020, were observed on a counter in blue racks. One of the swabs was observed to have two different requisition labels, Patient #11778097 requisition label was underneath Patient #11782778 requisition label, and Patient #11782778's accession label was on the swab (Accession #1103298501). During a tour of the receiving area on 11/17/2020 at 4:22 pm, a swab for Patient #11778097 was observed in the freezer. The swab was labeled with the patient requisition label (#11778097) and their corresponding accession label (Accession #1103316031). The swab with the two different requisition labels was not rejected (requisition label #11778097 and #11782778). 2. Review of the laboratory's "Specimen Acceptance and Rejections" (SOP #: GENFL-7; effective date: 09/08/2020) policy did not include procedures for specimen swabs labeled with two different patient names. Note: this policy stated, "Copy of version 2.0 (ready for lab director approval)." The policy had been modified and the laboratory director had not reviewed and approved. 3. Review of the above mentioned patient test requisitions, instrument data and final test reports for COVID-19 included the following: Patient #11782778 (requisition number) requisition included a collection date/time of 11/13/2020 at 9:03 am and an accession label of #1103298501 (Container: Beaver swab); according to the QuantStudio 5 System data, the specimen was analyzed on 11/16/2020 at 16:40 hours; the final test report included COVID-19 result reported date/time of 11/16/2020 18:30 hours. Patient #11778097 (requisition number) requisition included a collection date/time of 11/13 /2020 at 8:01 am and an accession label of #1103316301 (Container: Beaver swab); according to the QuantStudio 5 System data, the specimen was analyzed on 11/16 /2020 at 16:40 hours; the final test report included COVID-19 result reported date /time of 11/16/2020 18:30 hours. The laboratory failed to establish written policies that ensure positive identification for specimens with two different patient requisition labels. 4. On 11/16/2020, the laboratory had received 157 specimens for COVID-19

	testing. From 10/03/2020 through 11/17/2020, the laboratory had analyzed 17,233 specimens. 5. During an interview on 11/17/2020 at 1:50 pm, the Team Lead of Accessioning provided the requisitions for the above-mentioned patients and stated the collection facility had labeled the specimen that way (the swab with two different requisition labels).
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to follow their procedures for monitoring, assessing and correcting identified problems. Findings included: 1. Review of the laboratory's procedure titled "Quality Management Plan" showed that under the section titled "Monthly Reviews" the laboratory has a "Form GENFL-32 Quality Assurance Plan Checklist" to document "laboratory performance in general and contains reviews and evaluations of pre-analytic, analytic and post-analytic metrics". The laboratory started testing on 10/02/2020 and no checklist for the month of October 2020 was available for review. 2. During an interview on 11/18/19 at 3:20 PM, the Technical Supervisor - A stated that the Quality Assurance Plan Checklist had not been filled out and that she was unable to locate the form.
D5300	PREANALYTIC SYSTEMS CFR(s): 493.1240 Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in 493.1241 and 493.1242, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the preanalytic systems and correct identified problems as specified in 493. 1249 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of manufacturer's instructions, laboratory's policy, test requisitions, patient test reports, instrument data, specimen receipt log sheets, and in interview with staff, the laboratory failed to meet the requirements of prenalytical systems, as follows: 1. The laboratory failed to ensure the test requisitions included the type of swabs (container) used for collection in order to ensure accurate and timely COVID-19 testing on the Panther Hologic analyzer for 25 of 25 patients from 10/2020. Refer to D5305. 2. The laboratory failed to follow their own written policy for specimen receipt and handling for 3 of 3 days specimens were received from outside clients for COVID-19 testing (10/02/2020, 10/04/2020, 10/06/2020). Refer to D5311, I. 3. The laboratory failed to ensure specimens for COVID-19 testing had not exceeded their stability for 9 of 10 Runmei swabs and 1 of 10 Beaver swabs (sampling from 10/09 /2020 and 10/10/2020). Refer to D5311, II. 4. The laboratory failed to verify shipping /transport conditions for specimens (from outside clients) maintained temperature according to manufacturer's instructions for 1,254 of 1,254 specimens observed on 11

	/17/2020 and 9 of 9 specimens from a sampling received 10/09/2020. Refer to D5311, III. 5. The laboratory's preanalytical policies and procedures were inconsistent with manufacturer's instructions for Beaver swabs. Refer to D5311, IV. 6. The laboratory failed to document the time patient COVID-19 specimens were received from outside clients for 31 of 31 specimens from 10/2020. Refer to D5313.
D5305	TEST REQUEST CFR(s): 493.1241(c) The laboratory must ensure the test requisition solicits the following information: (1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. (2) The patient's name or unique patient identifier. (3) The sex and age or date of birth of the patient. (4) The test(s) to be performed. (5) The source of the specimen, when appropriate. (6) The date and, if appropriate, time of specimen collection. (7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. (8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, laboratory's policy, test requisitions, patient test reports, instrument data, and in interview with staff, the laboratory failed to ensure the test requisitions included the type of swabs (container) used for collection in order to ensure accurate and timely COVID-19 testing on the Panther Hologic analyzer for 25 of 25 patients from 10/2020. Findings included: 1. Review of manufacturer's instructions for collection devices accepted by the laboratory revealed the following stability timeframes: Single-use Samplers Runmei AMIES - "The collected samples can be stored at regular storage temperature (between 20-37C) for at least 96 hours, long-term storage should be placed in low-temperature conditions below -20C, -70C or store at freezing level -196C" (C = degrees Celsius). Aptima Mutlitest - "After collection, specimens in the Aptima Multitest Transport Tube may be stored at 2C to 30C up to 6 days." Copan ESwab - " ...If immediate delivery or processing is delayed, then specimens should be refrigerated at 4 - 8C or stored at room temperature (20 - 25C) and processed within 48 hours except for Neisseria gonorrhoeae [sic] cultures, which should be processed within 24 hours." Beaver - "RNA Viral Preservative performance was tested by detecting different RNA virus concentration diluted in the target reagent and placed at room temperature (20 to 25C) and -20C for 1 to 7 days ...The experimental data provide the evidence that viral RNA samples stored in the Preservative were highly stable at RT for at least 7 days comparing with stored at -20C." Review of patient requisitions did not solicit the swab type to ensure specimens were analyzed within the above timeframes. 2. Review of the laboratory's policy "Specimen Collection and Shipping" (SOP #: GENFL-43; no effective date), stated "D. Specimen Storage: 1. After collection, specimens must be stored in the appropriate storage temperature conditions listed below. Storage temperatures are dependent on specimen type and collection container/kit. 2. Specimens must be received in the laboratory within the specimen's stability. Specimen stability is dependent upon specimen type and collection container/kit. Specimens should be shipped daily to avoid specimen rejection. Collection Container

/Kit: Copan eSwab, Storage Temperature Range: 20-25C, Specimen Stability 48 hours; Collection Container/Kit: Aptima Multitest ,Storage Temperature Range: 2-30C, Specimen Stability 6 days; Collection Container/Kit: Remel Microtest M4RT, Specimen Storage Temperature Range: 20-25C, Specimen Stability: 48 hours; Collection Container/Kit: Run Mei Amies, Specimen Storage Temperature Range: 20-37C, Specimen Stability: 96 hours; Collection Container/Kit: Beaver, Specimen Storage Temperature Range: 15-30C, Specimen Stability: 7 days." The policy was not signed and approved by the laboratory director. 3. Review of patient test requisitions, test reports, and instrument data for COVID-19 specimens received 10/02/2020, 10/06 /2020, and 10/09/2020, revealed the laboratory did not ensure the swab type was solicited in order to meet stability timeframes when analyzed on the Panther Hologic, as follows (sampling of patients): Patient #20132819 - collected 9/29/2020 at 1:04 pm; Code: 401310, Tube: SWAB, Description: SARS-CoV-2, Additional Info: Coronavirus SARS-CoV-2 Swab; the Accession label: CONT:SWAB, WL: COVID PANTHER; received 10/02/2020. Panther Hologic results report revealed the specimen was analyzed 10/03/2020 at 2:35 am. Final test report included "SPECIMEN TYPE: SW-Swab; SOURCE: VTM." Patient #20132737 - collected 9/30 /2020 at 11:33 am; Code: 401310, Tube: SWAB, Description: SARS-CoV-2, Additional Info: Coronavirus SARS-CoV-2 Swab; the Accession label: CONT: SWAB, WL: COVID PANTHER; received 10/02/2020. Panther Hologic results report revealed the specimen was analyzed 10/03/2020 at 1:10 am. Final test report included "SPECIMEN TYPE: SW-Swab; SOURCE: VTM." Patient #20132713 - collected 9/28/2020 at 12:00 pm; Code: 401310, Tube: SWAB, Description: SARS-CoV-2, Additional Info: Coronavirus SARS-CoV-2 Swab; the Accession label: CONT:SWAB, WL: COVID PANTHER; received 10/02/2020. Panther Hologic results report revealed the specimen was analyzed 10/03/2020 at 12:45 am. Final test report included "SPECIMEN TYPE: SW-Swab; SOURCE: VTM." Patient #20132796 - collected 10/01/2020 at 12:06 pm; Microogranisms: SARS-CoV-2; Order Code: 401310; Site: Oropharyngeal; Sample Type: Swab; the Accession label: CONT: SWAB, WL: COVID PANTHER; received 10/02/2020. Panther Hologic results report revealed the specimen was analyzed 10/03/2020 at 2:10 am. Final test report included "SPECIMEN TYPE: SW-Swab; SOURCE: VTM." Patient #20132717 - collected 9/28/2020 at 2:23 am; Code: 401310, Tube: SWAB, Description: SARS-CoV-2, Additional Info: Coronavirus SARS-CoV-2 Swab; the Accession label: CONT:SWAB, WL: COVID 19 QS; received 10/02/2020. Panther Hologic results report revealed the specimen was analyzed 10/03/2020 at 12:40 am. Final test report included "SPECIMEN TYPE: SW-Swab; SOURCE: VTM." Patient #20132718 - collected 9/28/2020 at 2:19 am; Code: 401310, Tube: SWAB, Description: SARS-CoV-2, Additional Info: Coronavirus SARS-CoV-2 Swab; the Accession label: CONT:SWAB, WL: COVID 19 QS; received 10/02/2020. Panther Hologic results report revealed the specimen was analyzed 10/03/2020 at 12:40 am. Final test report included "SPECIMEN TYPE: SW-Swab; SOURCE: VTM." Patient #20132720 - collected 9/28/2020 at 2:26 am; Code: 401310, Tube: SWAB, Description: SARS-CoV-2, Additional Info: Coronavirus SARS-CoV-2 Swab; the Accession label: CONT:SWAB, WL: COVID 19 QS; received 10/02/2020. Panther Hologic results report revealed the specimen was analyzed 10/03/2020 at 12:40 am. Final test report included "SPECIMEN TYPE: SW-Swab; SOURCE: VTM." Patient #20132846 - collected 9/30/2020 at 12:00 am; Code: 401310, Tube: SWAB, Description: SARS-CoV-2, Additional Info: Coronavirus SARS-CoV-2 Swab; the Accession label: CONT:SWAB, WL: COVID PANTHER; received 10/02/2020. Panther Hologic results report revealed the specimen was analyzed 10/03/2020 2:25 am. Final test report included "SPECIMEN TYPE: SW-Swab; SOURCE: VTM." Patient #20132790 - collected 9/30/2020 at 11:37 am; Code: 401310, Tube: SWAB, Description: SARS-

CoV-2, Additional Info: Coronavirus SARS-CoV-2 Swab; the Accession label: CONT:SWAB, WL: COVID PANTHER; received 10/02/2020. Panther Hologic results report revealed the specimen was analyzed 10/03/2020 at 2:00 am. Final test report included "SPECIMEN TYPE: SW-Swab; SOURCE: VTM." Patient #2013505601 - collected 10/02/2020 at 2:02 pm; Code: 401310, Tube: SWAB, Description: SARS-CoV-2, Additional Info: Coronavirus SARS-CoV-2 Swab; the Accession label: CONT:SWAB, WL: COVID 19 QS; received 10/06/2020. Panther Hologic results report revealed the specimen was analyzed 10/06/2020 at 12:30 am. Final test report included "SPECIMEN TYPE: SW-Swab; SOURCE: VTM." Patient #20134964 - collected 10/02/2020 at 1:34 pm; Code: 401310, Tube: SWAB, Description: SARS-CoV-2, Additional Info: Coronavirus SARS-CoV-2 Swab; the Accession label: CONT:SWAB, WL: COVID 19 QS; received 10/06/2020. Panther Hologic results report revealed the specimen was analyzed 10/06/2020 at 3:15 am. Final test report included "SPECIMEN TYPE: SW-Swab; SOURCE: VTM." Patient #20135342 - collected 09/29/2020 at 10:16 am; Code: 401310, Tube: SWAB, Description: SARS-CoV-2, Additional Info: Coronavirus SARS-CoV-2 Swab; the Accession label: CONT:SWAB, WL: COVID PANTHER; received 10/06/2020. Panther Hologic results report revealed the specimen was analyzed 10/06/2020 at 2:45 am. Final test report included "SPECIMEN TYPE: SW-Swab; SOURCE: VTM." Patient #20135371 - collected 9/29/2020 at 8:18 am; Code: 401310, Tube: SWAB, Description: SARS-CoV-2, Additional Info: Coronavirus SARS-CoV-2 Swab; the Accession label: CONT:SWAB, WL: COVID PANTHER; received 10/06/2020. Panther Hologic results report revealed the specimen was analyzed 10/06/2020 at 2:30 am. Final test report included "SPECIMEN TYPE: SW-Swab; SOURCE: VTM." Patient #20135348 - collected 9/29/2020 at 8:02 am; Code: 401310, Tube: SWAB, Description: SARS-CoV-2, Additional Info: Coronavirus SARS-CoV-2 Swab; the Accession label: CONT:SWAB, WL: COVID PANTHER; received 10/06/2020. Panther Hologic results report revealed the specimen was analyzed 10/06/2020 at 2:25 am. Final test report included "SPECIMEN TYPE: SW-Swab; SOURCE: VTM." Patient #20135419 - collected 9/29/2020 at 10:24 am; Code: 401310, Tube: SWAB, Description: SARS-CoV-2, Additional Info: Coronavirus SARS-CoV-2 Swab; the Accession label: CONT:SWAB, WL: COVID PANTHER; received 10/06/2020. Panther Hologic results report revealed the specimen was analyzed 10/06/2020 at 2:15 am. Final test report included "SPECIMEN TYPE: SW-Swab; SOURCE: VTM." Patient #20135357 - collected 9/28/2020 at 2:21 am; Code: 401310, Tube: SWAB, Description: SARS-CoV-2, Additional Info: Coronavirus SARS-CoV-2 Swab; the Accession label: CONT:SWAB, WL: COVID PANTHER; received 10/06/2020. Panther Hologic results report revealed the specimen was analyzed 10/06/2020 at 1:50 am. Final test report included "SPECIMEN TYPE: SW-Swab; SOURCE: VTM." Patient #20134549 - collected 9/29/2020 at 10:24 am; Code: 401310, Tube: SWAB, Description: SARS-CoV-2, Additional Info: Coronavirus SARS-CoV-2 Swab; the Accession label: CONT:SWAB, WL: COVID 19 QS; received 10/06/2020. Panther Hologic results report revealed the specimen was analyzed 10/06/2020 at 1:25 am. Final test report included "SPECIMEN TYPE: SW-Swab; SOURCE: VTM." Patient #20134464 - collected 9/29/2020 at 10:29 am; Code: 401310, Tube: SWAB, Description: SARS-CoV-2, Additional Info: Coronavirus SARS-CoV-2 Swab; the Accession label: CONT:SWAB, WL: COVID 19 QS; received 10/06/2020. Panther Hologic results report revealed the specimen was analyzed 10/06/2020 at 1:15 am. Final test report included "SPECIMEN TYPE: SW-Swab; SOURCE: VTM." Patient #20135069 - collected 10/02/2020 at 2:49 pm; Code: 401310, Tube: SWAB, Description: SARS-CoV-2, Additional Info: Coronavirus SARS-CoV-2 Swab; the Accession label: CONT:SWAB, WL: COVID 19 QS; received 10/06/2020. Panther Hologic results report revealed the specimen was analyzed 10/06/2020 at 12:50 am.

	Final test report included "SPECIMEN TYPE: SW-Swab; SOURCE: VTM." Patient #20135373 - collected 9/29/2020 at 10:26 am; Code: 401310, Tube: SWAB, Description: SARS-CoV-2, Additional Info: Coronavirus SARS-CoV-2 Swab; the Accession label: CONT:SWAB, WL: COVID PANTHER; received 10/06/2020. Panther Hologic results report revealed the specimen was analyzed 10/06/2020 at 2:00 am. Final test report included "SPECIMEN TYPE: SW-Swab; SOURCE: VTM." Patient #20134602 - collected 9/29/2020 at 7:43 am; Code: 401310, Tube: SWAB, Description: SARS-CoV-2, Additional Info: Coronavirus SARS-CoV-2 Swab; the Accession label: CONT:SWAB, WL: COVID 19 QS; received 10/06/2020. Panther Hologic results report revealed the specimen was analyzed 10/06/2020 at 3:30 am. Final test report included "SPECIMEN TYPE: SW-Swab; SOURCE: VTM." Patient #20135490 - collected 9/29/2020 at 10:40 am; Code: 401310, Tube: SWAB, Description: SARS-CoV-2, Additional Info: Coronavirus SARS-CoV-2 Swab; the Accession label: CONT:SWAB, WL: COVID PANTHER; received 10/06/2020. Panther Hologic results report revealed the specimen was analyzed 10/06/2020 at 1:25 am. Final test report included "SPECIMEN TYPE: SW-Swab; SOURCE: VTM." Patient #20136956 - collected 10/06/2020 at 10:40 am; Microogranisms: SARS-CoV-2; Order Code: 401310; Site: Nasal Mid-Turbinate; Sample Type: Swab; the Accession label: CONT:SWAB, WL: COVID PANTHER; received 10/09/2020. Panther Hologic results report revealed the specimen was analyzed 10/10/2020 at 2:32 pm. Final test report included "SPECIMEN TYPE: SW-Swab; SOURCE: VTM." Patient #20136924 - collected 10/06/2020 at 9:40 am; Microogranisms: SARS-CoV-2; Order Code: 401310; Site: Nasal Mid-Turbinate; Sample Type: Swab; the Accession label: CONT:SWAB, WL: COVID PANTHER; received 10/09/2020. Panther Hologic results report revealed the specimen was analyzed 10/10/2020 at 2:27 pm. Final test report included "SPECIMEN TYPE: SW-Swab; SOURCE: VTM." Patient #20136958 - collected 10/06/2020 at 9:30 am; Microogranisms: SARS-CoV-2; Order Code: 401310; Site: Nasal Mid-Turbinate; Sample Type: Swab; the Accession label: CONT:SWAB, WL: COVID PANTHER; received 10/09/2020. Panther Hologic results report revealed the specimen was analyzed 10/10/2020 at 2:32 pm. Final test report included "SPECIMEN TYPE: SW-Swab; SOURCE: VTM." Patient #20132717, Patient #20132718, Patient #20132720, Patient #2013505601, Patient #20134964, Patient #20134549, Patient #20134464, Patient #20135069, and Patient #20134602 worklist was for QuantStudio analyzer but specimens were analyzed on the Panther Hologic. The laboratory did not ensure the swab type was solicited on the test requisitions in order to meet the stability timeframes when tested. 4. From 10/03/2020 through 11/17/2020, the laboratory had analyzed 17,233 specimens. 5. During an interview on 11/17/2020 at 4:02 pm, Technical Supervisor - A was asked what type of swab is "VTM" (as printed on the final reports), she stated it might be Beaver or Runmeis. During an interview on 11/19/2020 at 9:33 am, a staff from accessioning was asked what type of swab was "Code 401310" (as printed on the requisitions), he stated Runmeis or VTM, which were maybe Aptimas. He stated the code meant the swab was meant to be analyzed on the Panther (Hologic). The laboratory was unable to determine the swab types that were analyzed on the Panther Hologic in order to assess stability timeframes as outlined by the manufacturer. Word Key: CONT = container WL = worklist QS = QuantStudio RT = room temperature
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when

appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.

This STANDARD is not met as evidenced by:
I. Based on review of the laboratory's policy, patient test reports, specimen receipt log sheets, and in interview with staff, the laboratory failed to follow their own written policy for specimen receipt and handling for 3 of 3 days specimens were received from outside clients for COVID-19 testing (10/02/2020, 10/04/2020, 10/06/2020). Findings included: 1. Review of the laboratory's policy "Specimen Receipt and Handling" (SOP #: GENFL-5; effective dates: 9/8/2020 and 11/11/2020) stated, "III. PROCEDURE F. Record the measured temperature, date, time, number of packages, courier service name, and receiving personnel on the SharePoint Molecular Tox Receipt Log along with the package(s) tracking number and client name. G. Receipt log will be monitored for non-compliance. If repeated trends of non-compliance are found with a service, the laboratory will reevaluate shipping and transport procedures." 2. Review of patient test reports with received dates of 10/02/2020, 10/04/2020, and 10/06/2020 did not include documentation of temperatures, times, number of packages from clients, courier service names, receiving personnel, package tracking numbers and client names in SharePoint Molecular Receipt Log, as required by the laboratory's written policy mentioned above. The following is a sampling of specimens received for COVID-19 testing 10/02/2020, 10/04/2020, and 10/06/2020: Patient #20132866; received date 10/02/2020 Patient #20132819; received date 10/02/2020 Patient #20132864; received date 10/02/2020 Patient #20132737; received date 10/02/2020 Patient #20132713; received date 10/02/2020 Patient #20132796; received date 10/02/2020 Patient #20132717; received date 10/02/2020 Patient #20132718; received date 10/02/2020 Patient #20132720; received date 10/02/2020 Patient #20132846; received date 10/02/2020 Patient #20134160; received date 10/04/2020 Patient #20134094; received date 10/04/2020 Patient #20134192; received date 10/04/2020 Patient #20134195; received date 10/04/2020 Patient #20134290; received date 10/04/2020 Patient #20134313; received date 10/04/2020 Patient #20134324; received date 10/04/2020 Patient #20134169; received date 10/04/2020 Patient #20135056; received date 10/06/2020 Patient #20134964; received date 10/06/2020 Patient #20135342; received date 10/06/2020 Patient #20135371; received date 10/06/2020 Patient #20135348; received date 10/06/2020 Patient #20135419; received date 10/06/2020 Patient #20135357; received date 10/06/2020 Patient #20134549; received date 10/06/2020 Patient #20134464; received date 10/06/2020 Patient #20135069; received date 10/06/2020 Patient #20135373; received date 10/06/2020 Patient #20134602; received date 10/06/2020 Patient #20135490; received date 10/06/2020 From 10/03/2020 through 11/17/2020, the laboratory had analyzed 17,233 specimens. 3. During an interview on 11/18/2020 at 11:45 am, a staff from the accessioning team stated they began documenting client names and package tracking numbers on 10/07/2020 in an Excel sheet. He stated the SharePoint was not operational until 10/12/2020 and they transcribed information from Excel sheets to the SharePoint then. He confirmed that documentation of shipments received prior to 10/07/2020 was not available. II. Based on review of the laboratory's policy, manufacturer's instructions, test requisitions, instrument data, patient test reports, and in interview with staff, the laboratory failed to ensure specimens for COVID-19 testing had not exceeded their stability for 9 of 10 Runmei swabs and 1 of 10 Beaver swabs (sampling from 10/09/2020 and 10/10/2020). Findings included: 1. Review of the laboratory's policy "Specimen Collection and Shipping" (SOP #: GENFL-43; no effective date), stated "2. Specimens must be received in the laboratory within the specimen's stability.

Specimen stability is dependent upon specimen type and collection container/kit. Specimens should be shipped daily to avoid specimen rejection. Collection Container /Kit: Copan eSwab, Storage Temperature Range: 20-25C, Specimen Stability 48 hours; Collection Container/Kit: Aptima Multitest ,Storage Temperature Range: 2-30C, Specimen Stability 6 days; Collection Container/Kit: Remel Microtest M4RT, Specimen Storage Temperature Range: 20-25C, Specimen Stability: 48 hours; Collection Container/Kit: Run Mei Amies, Specimen Storage Temperature Range: 20-37C, Specimen Stability: 96 hours; Collection Container/Kit: Beaver, Specimen Storage Temperature Range: 15-30C, Specimen Stability: 7 days." The laboratory director had not approved and signed the policy. 2. Review of manufacturer's instructions for collection devices accepted by the laboratory revealed the following stability timeframe's: Single-use Samplers Runmei AMIES - "The collected samples can be stored at regular storage temperature (between 20-37C) for at least 96 hours, long-term storage should be placed in low-temperature conditions below -20C, -70C or store at freezing level -196C." Beaver - "RNA Viral Preservative performance was tested by detecting different RNA virus concentration diluted in the target reagent and placed at room temperature (20 to 25C) and -20C for 1 to 7 days ...The experimental data provide the evidence that viral RNA samples stored in the Preservative were highly stable at RT for at least 7 days comparing with stored at -20C." Note: The laboratory's policy was not consistent with the manufacturer's instructions for temperature storage (policy: 15-30C; Beaver: 20-25C). 3. Review of test requisitions, instrument data (Panther Hologic and QuantStudio), and final test reports revealed the laboratory analyzed COVID-19 specimens that had exceeded their stability (Runmei swab: 96 hours; Beaver swab: 7 days) according to the manufacturer's instructions, as follows (sampling): Patient #20137013 - Source: Run Mei swab; collected 10/06/2020 at 11:33 am; received date 10/09/2020; analyzed 10/10/2020 at 2:22 pm; 98 hours and 49 minutes of elapsed time between collection and analysis (Panther Hologic). Patient #20137019 - Source: Run Mei swab; collected 10/06/2020 at 10:05 am; received date 10/09/2020; analyzed 10/10/2020 at 2:22 pm; 100 hours and 17 minutes of elapsed time between collection and analysis (Panther Hologic). Patient #20137031 - Source: Run Mei swab; collected 10/06/2020 at 11:15 am; received date 10/09/2020; analyzed 10/10/2020 at 2:17 pm; 99 hours and 2 minutes of elapsed time between collection and analysis (Panther Hologic). Patient #20137036 - Source: Run Mei swab; collected 10/06/2020 at 11:00 am; received date 10/09/2020; analyzed 10/10/2020 at 2:12 pm; 99 hours and 12 minutes of elapsed time between collection and analysis (Panther Hologic). Patient #20137074 - Source: Run Mei swab; collected 10/06/2020 at 11:37 am; received date 10/09/2020; analyzed 10/10/2020 at 2:07 pm; 98 hours and 30 minutes of elapsed time between collection and analysis (Panther Hologic). Patient #20137007 - Source: Run Mei swab; collected 10/06/2020 at 9:50 am; received date 10/09/2020; analyzed 10/10/2020 at 2:22 pm; 100 hours and 17 minutes of elapsed time between collection and analysis (Panther Hologic). Patient #20137077 - Source: Run Mei swab; collected 10/06/2020 at 10:00 am; received date 10/09/2020; analyzed 10/10/2020 at 2:07 pm; 100 hours and 7 minutes of elapsed time between collection and analysis (Panther Hologic). Patient #20137086 - Source: Run Mei swab; collected 10/06/2020 at 9:30 am; received date 10/09/2020; analyzed 10/10/2020 at 2:12 pm; 100 hours and 42 minutes of elapsed time between collection and analysis (Panther Hologic). Patient #20137055 - Source: Run Mei swab; collected 10/06/2020 at 11:10 am; received date 10/09/2020; analyzed 10/10/2020 at 2:17 pm; 99 hours and 7 minutes of elapsed time between collection and analysis (Panther Hologic). Patient #20136110 - Source: Beaver swab; collected 10/01/2020 at 2:31 pm; received date 10 /07/2020; analyzed 10/09/2020 at 8:51 pm; 8 days, 6 hours and 20 minutes elapsed time between collection and analysis (QuantStudio). From 10/03/2020 through 11/17 /2020, the laboratory had analyzed 17,233 specimens. 4. During an interview on 11/17

/2020 at 4:02 pm, Technical Supervisor-A stated the laboratory discontinued accepting Runmei swabs because there were "issues." Technical Supervisor-A was asked what the issues were and she stated she was unsure. During an interview on 11/19/2020 at 10:16 am, Technical Supervisor-A confirmed specimens had been analyzed beyond their stability. Word Key: C = degrees Celsius III. Based on direct observation, review of laboratory's policy, manufacturer's instructions, client services manual, test requisitions, instrument data, final test reports, and in interview with staff, the laboratory failed to verify shipping/transport conditions for specimens (from outside clients) maintained temperature according to manufacturer's instructions for 1,254 of 1,254 specimens observed on 11/17/2020 and 9 of 9 specimens from a sampling received 10/09/2020. Findings included: 1. Review of the laboratory's policy "Specimen Receipt and Handling" (SOP #: GENFL-5; effective date with modification: 11/11/2020 - no laboratory director approval) stated, "III. PROCEDURE A. Samples are delivered to the accessioning department via courier (i.e., FedEx, UPS, or another courier service). C. Verify shipping containers are approved shipping containers outlined in GEN 8 Specimen Shipping & Transportation Procedure. Reject all specimens not received as required. E. Measure the temperature in the shipping container. 1. Measure the temperature using a IR thermometer by scanning the surface of the samples in each shipping container. 2. Specimen must be received within acceptable temperatures listed below ... Copan eSwab: 20 - 25C, Aptima Multitest 2 - 30C, MTM 2 - 25C, Beaver 15 - 30C." Run Mei was removed (11/11/2020), per manufacturer the temperature range was "between 20-37C" and Beaver manufacturer's instructions temperature range was "20-25C" not 15-30C. The laboratory had not verified shipping/transport conditions maintained manufacturer's storage temperature for the collection swabs mentioned in SOP #: GENFL-5. 2. Review of manufacturer's instructions for collection devices documented by the laboratory revealed the following stability timeframe's: Single-use Samplers Runmei AMIES - "The collected samples can be stored at regular storage temperature (between 20-37C) for at least 96 hours, long-term storage should be placed in low-temperature conditions below -20C, -70C or store at freezing level -196C." Beaver - "RNA Viral Preservative performance was tested by detecting different RNA virus concentration diluted in the target reagent and placed at room temperature (20 to 25C) and -20C for 1 to 7 days ...The experimental data provide the evidence that viral RNA samples stored in the Preservative were highly stable at RT for at least 7 days comparing with stored at -20C." Note: The laboratory's policy was not consistent with the manufacturer's instructions for temperature storage (policy: 15-30C; Beaver: 20-25C). The laboratory director had not approved and signed the policy. 3. During a tour of the accessioning area on 11/17/2020 at 10:39 am, patient Beaver swab specimens for COVID-19 testing were observed being received and accessioned by staff. The accessioning staff was observed opening UPS/FedEx bags/boxes of specimens in biohazard bags and obtaining a temperature via "Traceable fisherbrand" infrared thermometer. Temperatures were documented in a paper log (effective date 10/19/2020) and in SharePoint (effective date 10/12/2020) with client name, total specimen count, date and manifestation availability. Total specimens received 11/17/2020 was 617 (from TX, TN, and NV). On 11/18/2020 at 3:00 pm, patient Beaver swab specimens for COVID-19 testing were observed being received and accessioned by staff. The accessioning staff was observed opening UPS/FedEx bags/boxes of specimens in biohazard bags and obtaining a temperature via "Treaceable fisherbrand" infrared thermometer. Total specimens received 11/18/2020 was 637 specimens (from TX and NV). The laboratory had not verified shipping/transport conditions maintained manufacturer's storage temperature of 20-25C for Beaver collection swabs. According to documentation, the laboratory received Runmei swabs 10/09/2020 and shipping/transport conditions had not been verified to ensure storage

temperature of 20-37C was maintained. 4. Upon further review of the laboratory's client services manual (instructions to clients for specimen handling) revealed inconsistencies with the above-observed practice, as follows: "Specimen Transportation: COVID-19 specimens are transported to the laboratory by a local courier or commercial logistics company. That shipping container (Rubbermaid cooler or medium Styrofoam container) must include a temperature tracking device capable of recording the maximum and minimum temperature of the container throughout transportation to the laboratory ...Rejection Scenarios: A patient specimen will be rejected, and specimen collection will be required for the following: Specimen was not transported to the lab according to specimen transportation requirements." 5. Review of requisitions, instrument data, and final test reports for COVID-19 testing revealed the following sampling of patients received by the laboratory when shipping /transport conditions had not been verified to ensure storage temperature: Beaver swabs received 11/17/2020 at 10:45 am (observation by surveyor) and analyzed on the QuantStudio 11/18/2020 at 1:42 am - Patient #11035282 - collected 11/16/2020 at 3: 07 pm Patient #11035196 - collected 11/16/2020 at 2:18 pm Patient #11035168 - collected 11/16/2020 at 2:02 pm Patient #11035311 - collected 11/16/2020 at 3:31 pm Patient #11035332 - collected 11/16/2020 at 3:52 pm Patient #11035316 - collected 11 /16/2020 at 3:38 pm Patient #11035199 - collected 11/16/2020 at 2:20 pm Patient #11035208 - collected 11/16/2020 at 2:28 pm Patient #11035344 - collected 11/16 /2020 at 4:03 pm Patient #11035297 - collected 11/16/2020 at 3:20 pm Patient #11035340 - collected 11/16/2020 at 3:59 pm Patient #11035212 - collected 11/16 /2020 at 2:30 pm Patient #11035187 - collected 11/16/2020 at 2:18 pm Patient #11035329 - collected 11/16/2020 at 3:49 pm Patient #11035323 - collected 11/16 /2020 at 3:44 pm Patient #11035242 - collected 11/16/2020 at 2:46 pm Patient #11035321 - collected 11/16/2020 at 2:42 pm Patient #11035263 - collected 11/16 /2020 at 3:04 pm Patient #11035147 - collected 11/16/2020 at 1:52 pm Patient #11035151 - collected 11/16/2020 at 1:57 pm Runmei specimens received 10/09/2020 and analyzed on the Panther Hologic - Patient #20137013 -collected 10/06/2020 at 11: 33 am; analyzed 10/10/2020 at 2:22 pm Patient #20137019 -collected 10/06/2020 at 10:05 am; analyzed 10/10/2020 at 2:22 pm Patient #20137031 - collected 10/06/2020 at 11:15 am; analyzed 10/10/2020 at 2:17 pm Patient #20137036 - collected 10/06 /2020 at 11:00 am; analyzed 10/10/2020 at 2:12 pm Patient #20137074 - collected 10 /06/2020 at 11:37 am; analyzed 10/10/2020 at 2:07 pm Patient #20137007 - collected 10/06/2020 at 9:50 am; analyzed 10/10/2020 at 2:22 pm Patient #20137077 - collected 10/06/2020 at 10:00 am; analyzed 10/10/2020 at 2:07 pm Patient #20137086 - collected 10/06/2020 at 9:30 am; analyzed 10/10/2020 at 2:12 pm Patient #20137055 - collected 10/06/2020 at 11:10 am; analyzed 10/10/2020 at 2:17 pm From 10/03/2020 through 11/17/2020, the laboratory had received and analyzed 17,233 specimens. 6. Review of the laboratory verification studies revealed Beaver and Runmei swabs had not been verified in the systems used for COVID-19 testing. Refer to D5423. 7. During an interview on 11/17/2020 at 11:08 am, Technical Supervisor - A stated when they began testing (10/03/2020) they were receiving Aptima swabs or eSwab's but that stopped. They had not received Runmei swabs recently because there were issues and they had mostly received Beaver swabs. During an interview on 11/17/2020 at 11: 25 am, Technical Supervisor - A stated the shipping and stability studies of the collection devices (Beaver, Aptima, MTM, eSwab, and Run Mei) were ongoing and that she was almost done. She stated the studies had not been performed prior to COVID-19 testing. She stated she attempted conducting the shipping studies but there were issues with the temperature trackers and had restarted those studies. The laboratory had not verified their preanalytical system for shipping and handling all swab types prior to initiating COVID-19 testing to ensure accurate and reliable test results. IV. Based on review of manufacturer's instructions, laboratory's policy, client

services manual, and in interview with staff, the laboratory's preanalytical policies and procedures were inconsistent with manufacturer's instructions for Beaver swabs. Findings included: 1. Review of manufacturer's instructions for collection devices documented by the laboratory revealed the following stability timeframe's: Beaver - "RNA Viral Preservative performance was tested by detecting different RNA virus concentration diluted in the target reagent and placed at room temperature (20 to 25C) and -20C for 1 to 7 days ...The experimental data provide the evidence that viral RNA samples stored in the Preservative were highly stable at RT for at least 7 days comparing with stored at -20C." 2. Review of the laboratory's policy "Specimen Receipt and Handling" (SOP #: GENFL-5; effective date with modification: 11/11 /2020 - no laboratory director approval) stated, "III. PROCEDURE A. Samples are delivered to the accessioning department via courier (i.e., FedEx, UPS, or another courier service). C. Verify shipping containers are approved shipping containers outlined in GEN 8 Specimen Shipping & Transportation Procedure. Reject all specimens not received as required. E. Measure the temperature in the shipping container. 1. Measure the temperature using and IR thermometer by scanning the surface of the samples in each shipping container. 2. Specimen must be received within acceptable temperatures listed below ... Copan eSwab: 20 - 25C, Aptima Multitest 2 - 30C, MTM 2 - 25C, Beaver 15 - 30C." Beaver swabs temperature of "15-30C" was not consistent with manufacturer's instructions of 20-25C. Review of the laboratory's policy "Specimen Collection and Shipping" (SOP #: GENFL-43; no effective date), "2. Specimens must be received in the laboratory within the specimen's stability. Specimen stability is dependent upon specimen type and collection container/kit. Specimens should be shipped daily to avoid specimen rejection. Collection Container/Kit: Copan eSwab, Storage Temperature Range: 20-25C, Specimen Stability 48 hours; Collection Container/Kit: Aptima Multitest , Storage Temperature Range: 2-30C, Specimen Stability 6 days; Collection Container /Kit: Remel Microtest M4RT, Specimen Storage Temperature Range: 20-25C, Specimen Stability: 48 hours; Collection Container/Kit: Run Mei Amies, Specimen Storage Temperature Range: 20-37C, Specimen Stability: 96 hours; Collection Container/Kit: Beaver, Specimen Storage Temperature Range: 15-30C, Specimen Stability: 7 days." Beaver swabs temperature of "15-30C" was not consistent with manufacturer's instructions of 20-25C. 3. Review of client services manual (instructions for clients) stated, "Specimen Stability: Collection Container/Kit: Beaver Swab; Room Temperature Storage: 15-30C ..." and in section "Beaver Swab Collection Instructions: Store Specimen after collection at room temperature (15C to 30C) ...Specimen Transportation: The temperature of the container must maintain 15C to 30 C to be acceptable." The temperature of Beaver swabs in the client services manual was not consistent with the manufacturer's instructions of 20-25C. 4. Further review of client services manual (instructions for clients) stated, "Specimen Transportation: COVID-19 specimens are transported to the laboratory by a local courier or commercial logistics company. That shipping container (Rubbermaid cooler or medium Styrofoam container) must include a temperature tracking device capable of recording the maximum and minimum temperature of the container throughout transportation to the laboratory ...Rejection Scenarios: A patient specimen will be rejected, and specimen collection will be required for the following: Specimen was not transported to the lab according to specimen transportation requirements." The instructions to clients was not consistent with the laboratory's observed practice on 11 /17/2020 and 11/18/2020 (Refer to 5311, II). The laboratory's practice included clients submitting patient specimens in UPS/FedEx bags/boxes and the laboratory staff obtains a temperature via "Traceable fisherbrand" infrared thermometer. The specimens were not observed submitted in "Rubbermaid cooler or medium Styrofoam container" with "a temperature tracking device." 5. During the exit interview on 11/19

	/2020 at 3:36 pm, the inconsistencies of the laboratory's preanalytical policies and procedures was communicated to the Laboratory Director (via phone), Technical Supervisor-A, and Vice President.
D5313	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(b) The laboratory must document the date and time it receives a specimen. This STANDARD is not met as evidenced by: Based on review of final patient test reports and in interview with staff, the laboratory failed to document the time patient COVID-19 specimens were received from outside clients for 31 of 31 specimens from 10/2020. Findings included: 1. Review of a sampling of final patient test reports for COVID-19 testing from 10/2020 revealed no documentation of receipt time, as follows: Patient #20132866; received date 10/02 /2020 Patient #20132819; received date 10/02/2020 Patient #20132864; received date 10/02/2020 Patient #20132737; received date 10/02/2020 Patient #20132713; received date 10/02/2020 Patient #20132796; received date 10/02/2020 Patient #20132717; received date 10/02/2020 Patient #20132718; received date 10/02/2020 Patient #20132720; received date 10/02/2020 Patient #20132846; received date 10/02/2020 Patient #20134160; received date 10/04/2020 Patient #20134094; received date 10/04 /2020 Patient #20134192; received date 10/04/2020 Patient #20134195; received date 10/04/2020 Patient #20134290; received date 10/04/2020 Patient #20134313; received date 10/04/2020 Patient #20134324; received date 10/04/2020 Patient #20134169; received date 10/04/2020 Patient #20135056; received date 10/06/2020 Patient #20134964; received date 10/06/2020 Patient #20135342; received date 10/06/2020 Patient #20135371; received date 10/06/2020 Patient #20135348; received date 10/06 /2020 Patient #20135419; received date 10/06/2020 Patient #20135357; received date 10/06/2020 Patient #20134549; received date 10/06/2020 Patient #20134464; received date 10/06/2020 Patient #20135069; received date 10/06/2020 Patient #20135373; received date 10/06/2020 Patient #20134602; received date 10/06/2020 Patient #20135490; received date 10/06/2020 From 10/03/2020 through 11/17/2020, the laboratory had analyzed 17,233 specimens. 2. During an interview on 11/18/2020 at 11:45 am, a staff from the accessioning team stated they began documenting client names and package tracking numbers on 10/07/2020 in an Excel sheet. He stated the SharePoint was not operational until 10/12/2020 and they transcribed information from Excel sheets to the SharePoint then. He confirmed that documentation (including receipt time) of shipments received prior to 10/07/2020 was not documented.
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, laboratory's policy, test requisitions, patient test reports, instrument data, specimen receipt log sheets, and in interview with staff, the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicate, correct problems

	identified in the preanalytical systems, as follows: 1. The laboratory failed to ensure the test requisitions included the type of swabs (container) used for collection in order to ensure accurate and timely COVID-19 testing on the Panther Hologic analyzer for 25 of 25 patients from 10/2020. Refer to D5305. 2. The laboratory failed to follow their own written policy for specimen receipt and handling for 3 of 3 days specimens were received from outside clients for COVID-19 testing (10/02/2020, 10/04/2020, 10 /06/2020). Refer to D5311, I. 3. The laboratory failed to ensure specimens for COVID-19 testing had not exceeded their stability for 9 of 10 Runmei swabs and 1 of 10 Beaver swabs (sampling from 10/09/2020 and 10/10/2020). Refer to D5311, II. 4. The laboratory failed to verify shipping/transport conditions for specimens (from outside clients) maintained temperature according to manufacturer's instructions for 1,254 of 1,254 specimens observed on 11/17/2020 and 9 of 9 specimens from a sampling received 10/09/2020. Refer to D5311, III. 5. The laboratory's preanalytical policies and procedures were inconsistent with manufacturer's instructions for Beaver swabs. Refer to D5311, IV. 6. The laboratory failed to document the time patient COVID-19 specimens were received from outside clients for 31 of 31 specimens from 10/2020. Refer to D5313.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on record review and interview, the laboratory's quality assessment program failed to monitor and evaluate the overall quality of the analytic system and correct identified problems. Findings included: 1. The laboratory failed to have a policy or procedure for reporting patient results tested using the DTPM COVID-19 RT-PCR Test performed on the Quant Studio into the LIS (laboratory information system). Refer to D5403. 2. The laboratory failed to have documentation that the Laboratory Director of record with Clinical Laboratory Improvement Amendments (CLIA) approved, signed, and dated the procedure manual. Refer to D5407, I. 3. The laboratory failed to ensure COVID-19 test procedures and modification in procedures were approved, signed, and dated by the laboratory director. Refer to D5407, II. 4. The laboratory failed to verify the performance of the collection devices that were not included in the EUA's for COVID-19 testing. Refer to D5423. 5. The laboratory failed to document corrective actions when temperatures were out of range for their freezer, refrigerators and room temperatures from 10/2/2020 to 11/17/2020. Refer to D5781. 6. The laboratory failed to document personnel performing each step of testing (extraction, amplification, analyze, verify) for 5 of 5 of the DTPM COVID-19 RT-PCR Test performed on the Quant Studio (random sample October 2020-November 2020). Refer to D5787.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test

	procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on direct observation, review of policy and procedure and interview with staff the laboratory failed to have a policy or procedure for reporting patient results tested using the DTPM COVID-19 RT-PCR Test performed on the Quant Studio into the LIS (laboratory information system). 1. Direct observation on November 18, 2020 at 12:11 pm, the Technical Supervisor A (TS) entering results into the LIS the TS stated a .cvs file of the data is created then upload and the labs part is complete. 2. CMS requested a copy of a policy or procedure for reporting patient results tested using the DTPM COVID-19 RT-PCR Test performed on the Quant Studio into the LIS. No policy or procedure was provided. 3. In interview on November 19, 2020 at 10:40 am, the Technical Supervisor A stated the laboratory does not have a policy or procedure for reporting patient results tested using the DTPM COVID-19 RT-PCR Test performed on the Quant Studio into the LIS.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: I. Based on record review and interview, the laboratory failed to have documentation that the Laboratory Director of record with Clinical Laboratory Improvement Amendments (CLIA) approved, signed, and dated the procedure manual. Findings included: 1. Review of the letter of resignation from the Laboratory Director of record, showed she resigned effective 01/10/2020. Review of the Center for Medicare and Medicaid Services (CMS) website at the time of the survey, showed the laboratory director of record was the laboratory director who resigned. Review of the contract for the new Laboratory Director showed he signed and dated the contract on 06/29/2020. Review of the laboratory's procedures showed that the new Laboratory Director had signed all the procedures. 2. During an interview on 11/18/2020 at 10:18 AM, the Technical Supervisor - A stated the procedures were signed by the new Laboratory Director. II. Based on review of laboratory policies and in interview with staff, the laboratory failed to ensure COVID-19 test procedures and modification in

	procedures were approved, signed, and dated by the laboratory director. Findings: 1. During an interview on 11/17/2020 at 11:43 am, Technical Supervisor - A stated the laboratory began receiving specimens for COVID-19 testing on 10/02/2020. The analyzers used for testing were QuantStudio and Panther Hologic. Review of instrument data revealed the Panther system was used to analyze beginning on 10/03 /2020 and the QuantStudio was used to analyze beginning on 10/05/2020. 2. Review of the laboratory's policies did not include laboratory director approval and signature /date, as follows: "GENFL-5 Specimen Receipt and Handling: ... Comments for version 1.1 (this revision) remove RunMei" - the revision was done on 11/11/2020 and the last signature of the laboratory director was on 09/03/2020. "PIFL-10 Aptima Multitest Swab Specimen Collection Kit for SARS-CoV-2 Specimen Collection: Copy of version 1.0 (ready for lab director approval)" - the policy was created on 10 /27/2020. "PIFL-15 Aptima SARS-CoV-2 Assay (Panther System): Copy of version 1.0 (ready for lab director approval)" - the policy was created on 10/27/2020. "GENFL-7 Specimen Acceptance and Rejections: Copy of version 2.0 (ready for lab director approval)" - the revision was done on 11/11/2020 and the last signature of the laboratory director was on 09/03/2020. "GENFL-6 Accessioning and data entry" - policy was signed by the laboratory on 11/18/2020 not prior to receiving/accessioning specimens for COVID-19 testing (10/02/2020). 3. During an interview on 11/17/2020 at 11:00 am, Technical Supervisor - A confirmed that writing policies and conducting studies were ongoing.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on review of test requisitions, instrument data, patient test reports, Emergency Use Authorization's (EUA) for COVID-19 testing, Technical Bulletin, and in interview with staff, the laboratory failed to verify the performance of the collection devices that were not included in the EUA's for COVID-19 testing. Findings included: 1. Review of EUA's for Aptima SARS-CoV-2 Assay (used on Panther Hologic) and Tide Laboratories DTPM (used on QuantStudio) for specimen collection devices revealed the following: Aptima SARS-CoV-2 Assay listed alternative collection devices but did not include the Run Mei swabs. In an email (7/28/2020) from a Hologic Field Application Specialist a Technical Bulletin included a "do not use" list and "Hunan Runmei Gene Technology Co. Single Use Samplers (Inactivated)" was listed. DTPM protocol was established using the eSwab collection device. According to their protocol for alternative swab types, it stated, "While the swabs and media listed in this protocol are FDA approved for collection and transport, the performance for all FDA approved devices has not been established for use with this protocol." The laboratory had not verified the performance of Runmei swabs on the Panther Hologic

	and Beaver swabs on the QuantStudio. 2. Review of patient swabs and testing documentation (requisitions, instrument data, and patient test reports) revealed the following: Specimens received on 10/02/2020, 10/06/2020, and 10/09/2020 did not include documentation of the type of swab analyzed on the Panther Hologic analyzer for COVID-19 testing (Refer to 5305). It could not be determined whether the swab type was acceptable according to Panther Hologic EUA. Specimens received on 10/09 /2020 included documentation of collection in Run Mei swabs analyzed on the Panther Hologic and the laboratory had not verified the performance of the swabs. (Note: specimens exceeded their 96 hour stability and were analyzed/reported, Refer to D5311, II). Specimens received on 11/17/2020 included documentation of collection in Beaver swabs and were analyzed on the QuantStudio (Refer to D5311, III). The laboratory had not verified the performance of the swabs. From 10/03/2020 through 11/17/2020, the laboratory had received and analyzed 17,233 specimens. 3. During an interview on 11/17/2020 at 11:08 am, Technical Supervisor -A stated when they began testing (10/03/2020) they were receiving Aptima swabs or eSwab's but that stopped. They had not received Run Mei swabs recently because there were issues and they had mostly received Beaver swabs. During an interview on 11/17 /2020 at 11:25 am, Technical Supervisor - A stated the shipping and stability studies of the collection devices (Beaver, Aptima, MTM, eSwab, and Runmei) were ongoing and that she was almost done. She stated the studies had not been performed prior to COVID-19 testing. During an interview on 11/17/2020 at 4:02 pm, Technical Supervisor - A stated the laboratory discontinued accepting Run Mei swabs because there were "issues." Technical Supervisor - A was asked what the issues were and she stated she was unsure. (Note: the Runmei swabs were listed as part of the laboratory's "ongoing studies.")
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b) (1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to document corrective actions when temperatures were out of range for their freezer, refrigerators and room temperatures from 10/2/2020 to 11/17/2020. Findings included: 1. Review of the Freezer Temperature Log showed an acceptable range of less than minus 20 (-20) degrees Celsius (C). Review of the freezer temperature logs showed the following days where the temperature was above -20 degrees C and no corrective action was documented: Laboratory Freezer #1 -18 degrees C on 10/02/2020 -15 degrees C on 10 /05/2020 -16 degrees C on 10/06/2020 -13 degrees C on 10/07/2020 -16 degrees C on 10/08/2020 -17 degrees C on 10/09/2020 -17 degrees C on 10/12/2020 -18 degrees C on 10/13/2020 -17 degrees C on 10/14/2020 -18 degrees C on 10/15/2020 -16 degrees C on 10/16/2020 -16 degrees C on 10/19/2020 -18 degrees C on 10/20/2020 -17 degrees C on 10/21/2020 -18 degrees C on 10/22/2020 -17 degrees C on 10/23/2020

	-16 degrees C on 10/24/2020 -17 degrees C on 10/26/2020 -17 degrees C on 10/27 /2020 -16 degrees C on 10/28/2020 -17 degrees C on 10/29/2020 -17 degrees C on 10 /30/2020 -17 degrees C on 10/31/2020 -17 degrees C on 11/02/2020 -18 degrees C on 11/03/2020 -17 degrees C on 11/04/2020 -18 degrees C on 11/05/2020 -15 degrees C on 11/06/2020 -17 degrees C on 11/07/2020 -17 degrees C on 11/09/2020 -18 degrees C on 11/10/2020 -13 degrees C on 11/12/2020 -17 degrees C on 11/13/2020 -17 degrees C on 11/14/2020 -17 degrees C on 11/16/2020 -17 degrees C on 11/17/2020 2. During an interview on 11/17/2020 at 1:10 PM, the Technical Supervisor - A stated no corrective action was documented for temperatures not in the acceptable range. 3. Review of the Refrigerator Temperature Log showed an acceptable range of 2 - 8 C. Review of the refrigerator temperature logs showed the following minimum temperatures recorded were not in range and no corrective action was documented: Laboratory #3 Ref #2 1.8 degrees C on 11/06/2020 1.9 degrees C on 11/16/2020 Laboratory #3 Ref #2 1.9 degrees C on 11/12/2020 4. During an interview on 11/17 /2020 at 11:04 PM, the Technical Supervisor - A stated no corrective action was documented for temperatures not in the acceptable range. 5. Review of the Room Temperature Log showed an acceptable range of 18 - 25 degrees C. Review of the room temperature logs showed the following minimum temperatures recorded were not in range and no corrective action was documented: Laboratory #1 17.8 degrees C on 10/7/20 Laboratory #2 17.2 degrees C on 10/07/2020 17.9 degrees C on 10/09 /2020 17.9 degrees C on 10/20/2020 17.1 degrees C on 10/22/2020 17.2 degrees C on 10/25/2020 17.2 degrees C on 10/27/2020 17.1 degrees C on 10/28/2020 15.7 degrees C on 10/29/2020 16.5 degrees C on 10/30/2020 17.7 degrees C on 10/31/2020 16.1 degrees C on 11/02/2020 17.0 degrees C on 11/03/2020 17.7 degrees C on 11/06/2020 16.8 degrees C on 11/07/2020 17.0 degrees C on 11/08/2020 16.8 degrees C on 11/10 /2020 Laboratory #3 17.5 degrees C on 10/29/2020 17.6 degrees C on 11/02/2020 Laboratory #4 17.6 degrees C on 10/29/2020 Laboratory #5 17.9 degrees C on 10/15 /2020 17.1 degrees C on 10/16/2020 17.1 degrees C on 10/23/2020 17.0 degrees C on 11/5/2020 6. During an interview on 11/17/2020 at 11:04 AM, the Technical Supervisor - A stated no corrective action was documented for temperatures not in the acceptable range.
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: Based on record review, policy and procedure review, and interview with staff the laboratory failed to document personnel performing each step of testing (extraction, amplification, analyze, verify) for 5 of 5 of the DTPM COVID-19 RT-PCR Test performed on the Quant Studio (random sample October 2020-November 2020). 1. A random sample of batch record reports revealed the laboratory failed to document personnel performing each step of testing (extraction, amplification, analyze, verify) for 5 of 5 the DTPM COVID-19 RT-PCR Test on the Quant Studio (random sample October 2020-November 2020) a. Batch 101008122; date generated: 10/08/2020; specimen count 30; extraction and amplification personnel not documented. b. Batch

	0127100; date generated: 10/27/2020; specimen count 55; extraction, amplification and verification personnel not documented. c. Batch 01111107; date generated: 11/12/2020; specimen count 95; extraction, amplification and verification personnel not documented. d. Batch 01104105; date generated: 11/04/2020; specimen count 63; amplification and analyze personnel not documented. e. Batch 01002104; date generated: 10/05/2020; specimen count 94; analyze personnel not documented. 2. CMS requested a copy of a policy or procedure requiring documentation of personnel performing step of testing. No policy or procedure was provided. 3. In interview on November 19, 2020 at 10:40 am, the Technical Supervisor A stated the laboratory does not have a policy or procedure requiring documentation of personnel performing each step of testing.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on review of manufacturer's instructions, laboratory's policy, test requisitions, patient test reports, instrument data, specimen receipt log sheets, and personnel records, the laboratory director failed to provide overall management and direction, as evidenced by: 1. The laboratory did not have a qualified laboratory director to perform the overall management of the laboratory from 01/10/2020 through 06/29/2020. Refer to 6078. 2. The laboratory director failed to ensure testing systems for COVID-19 provide quality laboratory services for preanalytic and analytic phase of testing. Refer to D6082. 3. The Laboratory Director failed to ensure the quality assurance programs were maintained to assure the quality of laboratory services are provided and to identify failures in quality as they occur. Refer to D6094. 4. The laboratory director did not employ a sufficient amount of laboratory personnel with appropriate education, experience/training to accurately perform and report COVID-19 tests/test results. Refer to D6101.
D6078	LABORATORY DIRECTOR QUALIFICATIONS CFR(s): 493.1443 The laboratory director must be qualified to manage and direct the laboratory personnel and performance of high complexity tests and must be eligible to be an operator of a laboratory within the requirements of subpart R. (a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required; and (b) The laboratory director must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2) Be a doctor of medicine, a doctor of osteopathy or doctor of podiatric medicine licensed to practice medicine, osteopathy or podiatry in the State in which the laboratory is located; and (b)(2)(i) Have at least one year of laboratory training during medical residency (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or (b)(2)(ii) Have at

	least 2 years of experience directing or supervising high complexity testing; or (b)(3) Hold an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution and-- (b)(3)(i) Be certified and continue to be certified by a board approved by HHS; or (b)(3)(ii) Before February 24, 2003, must have served or be serving as director of a laboratory performing high complexity testing and must have at least-- (b)(3)(ii)(A) Two years of laboratory training or experience, or both; and (b)(3)(ii)(B) Two years of laboratory experience directing or supervising high complexity testing. (b)(4) Be serving as a laboratory director and must have previously qualified or could have qualified as a laboratory director under regulations at 42 CFR 493.1415, published March 14, 1990 at 55 FR 9538, on or before February 28, 1992; or (b)(5) On or before February 28, 1992, be qualified under State law to direct a laboratory in the State in which the laboratory is located; or (b)(6) For the subspecialty of oral pathology, be certified by the American Board of Oral Pathology, American Board of Pathology, the American Osteopathic Board of Pathology, or possess qualifications that are equivalent to those required for certification. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory did not have a qualified laboratory director to perform the overall management of the laboratory from 01/10 /2020 through 06/29/2020. Findings included: 1. Review of the letter of resignation from the Laboratory Director of record, showed she resigned effective 01/10/2020. Review of the Center for Medicare and Medicaid Services (CMS) website at the time of the survey, showed the laboratory director of record was the laboratory director who resigned. Review of the contract for the new Laboratory Director showed he signed and dated the contract on 06/29/2020. 2. During an interview on 11/19/2020 at 2:35 PM, the Technical Supervisor - A stated that they tried to get another Laboratory Director. During an interview on 11/19/2020 at 2:40 PM, the Vice President stated that they tried to get another Laboratory Director.
D6082	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1) The laboratory director must ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, laboratory's policy, test requisitions, patient test reports, instrument data, specimen receipt log sheets, EUA for COVID-19 testing, and Technical Bulletin, the laboratory director failed ensure testing systems for COVID-19 provide quality laboratory services for preanalytic and analytic phase of testing, as evidenced by: 1. The laboratory failed to ensure the test requisitions included the type of swabs (container) used for collection in order to ensure accurate and timely COVID-19 testing on the Panther Hologic analyzer for 25 of 25 patients from 10/2020. Refer to D5305. 2. The laboratory failed to follow their own written policy for specimen receipt and handling for 3 of 3 days specimens were received from outside clients for COVID-19 testing (10/02/2020, 10/04/2020, 10/06/2020). Refer to D5311, I. 3. The laboratory failed to ensure specimens for COVID-19 testing had not exceeded their stability for 9 of 10 Runmei swabs and 1 of 10 Beaver swabs

	(sampling from 10/09/2020 and 10/10/2020). Refer to D5311, II. 4. The laboratory failed to verify shipping/transport conditions for specimens (from outside clients) maintained temperature according to manufacturer's instructions for 1,254 of 1,254 specimens observed on 11/17/2020 and 9 of 9 specimens from a sampling received 10 /09/2020. Refer to D5311, III. 5. The laboratory's preanalytical policies and procedures were inconsistent with manufacturer's instructions for Beaver swabs. Refer to D5311, IV. 6. The laboratory failed to document the time patient COVID-19 specimens were received from outside clients for 31 of 31 specimens from 10/2020. Refer to D5313. 7. The laboratory failed to have a policy or procedure for reporting patient results tested using the DTPM COVID-19 RT-PCR Test performed on the Quant Studio into the LIS (laboratory information system). Refer to D5403. 8. The laboratory failed to have documentation that the Laboratory Director of record with Clinical Laboratory Improvement Amendments (CLIA) approved, signed, and dated the procedure manual. Refer to D5407, I and II. 9. The laboratory failed to verify the performance of the collection devices that were not included in the EUA's for COVID-19 testing. Refer to D5423. 10. The laboratory failed to document corrective actions when temperatures were out of range for their freezer, refrigerators and room temperatures from 10/2/2020 to 11/17/2020. Refer to D5781. 11. The laboratory failed to document personnel performing each step of testing (extraction, amplification, analyze, verify) for 5 of 5 of the DTPM COVID-19 RT-PCR Test performed on the Quant Studio (random sample October 2020-November 2020). Refer to D5787.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on record review and interview, the Laboratory Director failed to ensure the quality assurance programs were maintained to assure the quality of laboratory services are provided and to identify failures in quality as they occur. Findings: The Laboratory Director failed to ensure the laboratory followed their procedures for monitoring, assessing and correcting identified problems. Refer to D5291.
D6101	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(11) The laboratory director must employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart. This STANDARD is not met as evidenced by: Based on direct observations, review of the CMS-209, personnel records, and in interview with personnel, the laboratory director did not employ a sufficient amount of laboratory personnel with appropriate education, experience/training to accurately perform and report COVID-19 tests/test results. Findings included: 1. Review of the CMS-209 listed three testing personnel (TP -A, TP - B, TP - C) to analyze and report COVID-19 specimens. TP-A was listed as a Technical Supervisor (TS - A), and

	General Supervisor (GS - A). TP-C was listed as a Technical Supervisor (TS-C). The laboratory analyzed COVID-19 specimens on the Panther Hologic from 10/03/2020 through 10/10/2020 and discontinued using the Hologic. The laboratory analyzed COVID-19 specimens on the QuantStudio 5 system beginning 10/05/2020 and the QuantStudio 5 was the laboratory's current test method. 2. During an interview on 11/18/2020 at 10:30 am with TS - A, she revealed that TP-C/TS-C last day was 11/17/2020. (Note: personnel records revealed TP-C was not licensed by the State of Florida to perform testing or serve in a technical supervisory role) During an interview on 11/18/2020 at 11:45 am with TS - A, she stated that TP-B performed extractions and does not perform the amplification, analysis and verifying. TS-A stated she does all aspects of the testing for the QuantStudio (extractions, amplification, analysis, and verify). In addition to testing personnel responsibilities, TS-A was working on procedures and performing ongoing shipping/stability studies. 3. During a tour of the accessioning area on 11/17/2020 at 10:39 am, a total of 617 patient Beaver swab specimens for COVID-19 testing were observed being received and accessioned by staff. On 11/18/2020 at 3:00 pm, a total of 637 patient Beaver swab specimens for COVID-19 testing were observed being received and accessioned by staff. On 11/19/2020 at 11:09 am, a total of 609 patient Beaver swab specimens for COVID-19 testing were observed being received and accessioned by staff. From 10/03/2020 through 11/17/2020, the laboratory had analyzed 17,233 specimens. 4. During the exit interview on 11/19/2020 at 3:36 pm, the observed workload and lack of personnel were communicated to the laboratory director (via phone), TS-A/TP-A and the Vice President. The laboratory director did not employ a sufficient amount of laboratory personnel with appropriate education, experience/training to accurately perform and report COVID-19 tests/test results.
D6108	LABORATORY TECHNICAL SUPERVISOR CFR(s): 493.1447 The laboratory must have a technical supervisor who meets the qualification requirements of 493.1449 of this subpart and provides technical supervision in accordance with 493.1451 of this subpart. This CONDITION is not met as evidenced by: Based on personnel record review, review of license verification website, interview with laboratory staff and review of competency assessment records the laboratory failed to verify one of two Technical Supervisors were qualified for the position. Refer to D6111
D6111	TECHNICAL SUPERVISOR QUALIFICATIONS CFR(s): 493.1449 (a) The technical supervisor must possess a current license issued by the State in which the laboratory is located, if such licensing is required; and (b) The laboratory may perform anatomic and clinical laboratory procedures and tests in all specialties and subspecialties of services except histocompatibility and clinical cytogenetics services provided the individual functioning as the technical supervisor-- (b)(1) Is a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(2) Is certified in both anatomic and clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or Possesses qualifications that are equivalent to those required for such certification. (c) If the requirements of paragraph (b) of this

section are not met and the laboratory performs tests in the subspecialty of bacteriology, the individual functioning as the technical supervisor must-- (c)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (c)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (c)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (c)(2)(ii) Have at least one year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of bacteriology; or (c)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (c)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of bacteriology; or (c)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (c)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of bacteriology; or (c)(5)(i) Have earned a bachelor's degree in a chemical, physical, or biological science or medical technology from an accredited institution; and (c)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of bacteriology. (d) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of mycobacteriology, the individual functioning as the technical supervisor must-- (d)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (d)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (d)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor or podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (d)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycobacteriology; or (d)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (d)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycobacteriology; or (d)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (d)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycobacteriology; or (d)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (d)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of

mycobacteriology. (e) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of mycology, the individual functioning as the technical supervisor must-- (e)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (e)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (e)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (e)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycology; or (e)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (e)(3)(ii) Have at least 1 year of laboratory training or experience, or both in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycology; or (e)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (e)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycology; or (e)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (e)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycology. (f) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of parasitology, the individual functioning as the technical supervisor must-- (f)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (f)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (f)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (f)(2)(ii) Have at least one year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of parasitology; (f)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (f)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of parasitology; or (f)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (f)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of parasitology; or (f)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (f)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of

parasitology. (g) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of virology, the individual functioning as the technical supervisor must-- (g)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (g)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (g)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (g)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of virology; or (g)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (g)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of virology; or (g)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (g)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of virology; or (g)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (g)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of virology. (h) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of diagnostic immunology, the individual functioning as the technical supervisor must- (h)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (h)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (h)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (h)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing for the specialty of diagnostic immunology; or (h)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (h)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of diagnostic immunology; or (h)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (h)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing for the specialty of diagnostic immunology; or (h)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (h)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing for the specialty of diagnostic immunology. (i) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of chemistry, the individual functioning as the technical supervisor must-- (i)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (i)(1)(ii) Be certified in clinical pathology by the American

Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (i)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (i)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing for the specialty of chemistry; or (i)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (i)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of chemistry; or (i)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (i)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing for the specialty of chemistry; or (i)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (i)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing for the specialty of chemistry. (j) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of hematology, the individual functioning as the technical supervisor must-- (j)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (j)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (j)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (j)(2)(ii) Have at least one year of laboratory training or experience, or both, in high complexity testing for the specialty of hematology (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or (j)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (j)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of hematology; or (j)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (j)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing for the specialty of hematology; or (j)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (j)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing for the specialty of hematology. (k)(1) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of cytology, the individual functioning as the technical supervisor must-- (k)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (k)(1)(ii) Meet one of the following requirements-- (k)(1)(ii)(A) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (k)(1)(ii)(B) Be certified by the American Society of Cytology to practice cytopathology or possess qualifications that are equivalent to those required for such certification; (l) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of histopathology, the individual functioning as the technical supervisor must-- (l)(1) Meet one of the following requirements: (l)(1)(i)(A) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (l)(1)(i)(B) Be certified

in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; (l)(1)(ii) An individual qualified under 493.1449(b) or paragraph (l)(1) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraph (b) or (l)(1)(i)(B) of this section, the responsibility for examination and interpretation of histopathology specimens. (l)(2) For tests in dermatopathology, meet one of the following requirements: (l)(2)(i)(A) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located and-- (l)(2)(i)(B) Meet one of the following requirements: (l)(2)(i)(B)(1) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (l)(2)(i)(B)(2) Be certified in dermatopathology by the American Board of Dermatology and the American Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (l)(2)(i)(B)(3) Be certified in dermatology by the American Board of Dermatology or possess qualifications that are equivalent to those required for such certification; or (l)(2)(ii) An individual qualified under 493.1449(b) or paragraph (l)(2)(i) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraphs (b) or (l)(2)(i)(B) of this section, the responsibility for examination and interpretation of dermatopathology specimens. (l)(3) For tests in ophthalmic pathology, meet one of the following requirements: (l)(3)(i)(A) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located and-- (l)(3)(i)(B) Must meet one of the following requirements: (l)(3)(i)(B)(1) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (l)(3)(i)(B)(2) Be certified by the American Board of Ophthalmology or possess qualifications that are equivalent to those required for such certification and have successfully completed at least 1 year of formal post-residency fellowship training in ophthalmic pathology; or (l)(3)(ii) An individual qualified under 493.1449(b) or paragraph (1)(3)(i) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraphs (b) or (1)(3)(i)(B) of this section, the responsibility for examination and interpretation of ophthalmic specimens; or (m) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of oral pathology, the individual functioning as the technical supervisor must meet one of the following requirements: (m)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located and-- (m)(1)(ii) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (m)(2) Be certified in oral pathology by the American Board of Oral Pathology or possess qualifications for such certification; or (m)(3) An individual qualified under 493.1449(b) or paragraph (m)(1) or (2) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraphs (b) or (m)(1) or (2) of this section, the responsibility for examination and interpretation of oral pathology specimens. (n) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of radiobioassay, the individual functioning as the technical supervisor must-- (n)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (n)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess

qualifications that are equivalent to those required for such certification; or (n)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (n)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing for the specialty of radiobioassay; or (n)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (n)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of radiobioassay; or (n)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (n)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing for the specialty of radiobioassay; or (n)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (n)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing for the specialty of radiobioassay. (o) If the laboratory performs tests in the specialty of histocompatibility, the individual functioning as the technical supervisor must either-- (o)(1)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (o)(1)(ii) Have training or experience that meets one of the following requirements: (o)(1)(ii)(A) Have 4 years of laboratory training or experience, or both, within the specialty of histocompatibility; or (o)(1)(ii)(B)(1) Have 2 years of laboratory training or experience, or both, in the specialty of general immunology; and (o)(1)(ii)(B)(2) Have 2 years of laboratory training or experience, or both, in the specialty of histocompatibility; or (o)(2)(i) Have an earned doctoral degree in a biological or clinical laboratory science from an accredited institution; and (o)(2)(ii) Have training or experience that meets one of the following requirements: (o)(2)(ii)(A) Have 4 years of laboratory training or experience, or both, within the specialty of histocompatibility; or (o)(2)(ii)(B)(1) Have 2 years of laboratory training or experience, or both, in the specialty of general immunology; and (o)(2)(ii)(B)(2) Have 2 years of laboratory training or experience, or both, in the specialty of histocompatibility. (p) If the laboratory performs tests in the specialty of clinical cytogenetics, the individual functioning as the technical supervisor must-- (p)(1)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (p)(1)(ii) Have 4 years of training or experience, or both, in genetics, 2 of which have been in clinical cytogenetics; or (p)(2)(i) Hold an earned doctoral degree in a biological science, including biochemistry, or clinical laboratory science from an accredited institution; and (p)(2)(ii) Have 4 years of training or experience, or both, in genetics, 2 of which have been in clinical cytogenetics. (q) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of immunohematology, the individual functioning as the technical supervisor must-- (q)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (q)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (q)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (q)(2)(ii) Have at least one year of laboratory training or experience, or both, in high complexity testing for the specialty of immunohematology. Note: The technical supervisor requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the

	specialties or subspecialties of service. For example, an individual, who has a doctoral degree in chemistry and additionally has documentation of 1 year of laboratory experience working concurrently in high complexity testing in the specialties of microbiology and chemistry and 6 months of that work experience included high complexity testing in bacteriology, mycology, and mycobacteriology, would qualify as the technical supervisor for the specialty of chemistry and the subspecialties of bacteriology, mycology, and mycobacteriology. This STANDARD is not met as evidenced by: Based on personnel record review, review of the Florida Department of Health license verification website and interview with Technical Supervisor A (TS-A), Technical Supervisor C (TS-C) did not have a current Florida laboratory license. Findings Included: 1. Review of personnel records on the morning of November 17, 2020, revealed a job description for a Technical Supervisor position signed by TS-C on October 21, 2020. Records included a Bachelor of Science degree, a training checklist for the Panther Fusion SARS-Cov-2 signed October 3, 2020, and a training checklist for the Thermo-Fisher QuantStudio signed October 3, 2020. No record of a Florida laboratory supervisor license was found. 2. Review of the Florida Department of Health license verification website at 3pm on November 17, 2020, found no record of a Florida laboratory license issued to TS-C. 3. During interview on November 17, 2020, at 3pm, TS-A confirmed TS-C had not received a Florida laboratory license to date. TS-A stated TS-C applied for the license in early October and provided a document printed from the Florida Department of Health website that indicated TS-C applied for a technologist license. 4. Review of the personnel records on the morning of November 17, 2020, revealed a competency assessment for TS-A on the Thermo-Fisher QuantStudio was performed by TS-C on September 10, 2020. Laboratory procedure "GENFL-17 Personnel Training and Competency" states "E. Competency Assessors.....2. Peer reviewing personnel who do not meet the regulatory qualifications of a technical consultant, technical supervisor, or a general supervisor cannot be designated to perform competency assessments."
D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: Based on personnel record review, review of license verification website, review of test records and interview with laboratory staff, the laboratory failed to verify three of four Testing Personnel held a Florida laboratory license prior to performing laboratory testing. Refer to D6170
D6170	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(a) Each individual performing high complexity testing must possess a current license issued by the State in which the laboratory is located, if such licensing is required.

	This STANDARD is not met as evidenced by: Based on personnel record review, review of the Florida Department of Health license verification website, review of test records for the Thermo-Fisher QuantStudio and Panther Fusion SARS-Cov-2, and interview with Technical Supervisor A (TS-A), Testing Personnel C (TP-C) did not have a current Florida laboratory license at the time of the survey. The review also revealed Testing Personnel D (TP-D) and Testing Personnel E (TP-E) performed patient testing prior to receiving a Florida laboratory license. Findings Included: I. Testing Personnel C (TP-C is TS-C) a. Review of personnel records on the morning of November 17, 2020, revealed a job description for a Technical Supervisor position signed by TP-C /TS-C on October 21, 2020. Records included a Bachelor of Science degree, a training checklist for the Panther Fusion SARS-Cov-2 signed October 3, 2020, and a training checklist for the Thermo-Fisher QuantStudio signed October 3, 2020. No record of a Florida laboratory license was found. b. Review of the Florida Department of Health license verification website at 3pm on November 17, 2020, found no record of a Florida laboratory license issued to TP-C/TS-C. c. During interview on November 17, 2020, at 3pm, TS-A confirmed TP-C/TS-C had not received a Florida laboratory license to date. TS-A stated TP-C /TS-C applied for the license in early October and provided a document printed from the Florida Department of Health website that indicated TP-C /TS-C applied for a technologist license. d. Review of test records the afternoon of November 18, 2020, revealed TP-C/TS-C performed testing on the Panther Fusion on October 6, 2020; October 20, 2020; and October 31, 2020. Further review revealed TP-C/TS-C analyzed patient testing performed on the Thermo-Fisher QuantStudio on October 10, 2020 and October 27, 2020. 2. Testing Personnel D (TP-D) a. Review of personnel records the afternoon of November 18, 2020, revealed a job description for Testing Personnel signed by TP-D on October 21, 2020. Records included a Bachelor of Science degree, training checklist for Thermo-Fisher QuantStudio signed on October 3, 2020 and a competency assessment for Thermo-Fisher QuantStudio signed October 24, 2020. Records also included a Florida Clinical Laboratory Technologist license issued on November 2, 2020. b. Review of test records the afternoon of November 18, 2020, revealed TP-D performed extraction for the Thermo-Fisher QuantStudio on October 9, 2020. c. During interview November 18, 2020 at 11:45am, TS-A stated TP-D resigned early November 2020. TS-A confirmed TP-D performed patient testing prior to receiving a Florida laboratory license. 3. Testing Personnel E (TP-E) a. Review of personnel records the afternoon of November 18, 2020, revealed a job description for Testing Personnel signed by TP-E on October 21, 2020. Records included a Bachelor of Science degree, training checklists for the Thermo-Fisher QuantStudio signed October 3, 2020 and a competency assessment for the Thermo-Fisher QuantStudio signed October 24, 2020. Records also included a Florida Clinical Laboratory Technologist license issued on November 4, 2020. b. Review of test records the afternoon of November 18, 2020, revealed TP-E performed extraction for the Thermo-Fisher Quant Studio on October 15, 2020. c. During interview November 18, 2020 at 11:45am , TS-A stated TP-E resigned early November 2020. TS-A confirmed TP-E performed patient testing prior to receiving a Florida laboratory license.