Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D2212777	03/22/2022
Name of Provider or Supplier	**Street Address, City, State**	
Ottendorf Laboratories, Llc	1095 Investment Boulevard, Apex, NC	

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
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: Based on review of manufacturer's instructions, review of the laboratory procedure manual, and interviews with the TS (technical supervisor) and lab owner 3/22/22, the laboratory's procedures did not include all necessary criteria for specimen storage, acceptability and rejection for the current SARS-CoV-2 testing performed. Findings: Review of "CovidNow SARS-CoV-2 Assay Instructions for Use" revealed "3.3 STORAGE . 3.3.1 Specimens can be stored for up to 72 hours after collection. 3.3.2 If a delay is extraction is expected, store specimens at -70 degrees Celsius or lower." Review of laboratory procedure "SOP-10 CovidNow SARS-CoV-2 SOP Using King Fisher and Quant Studio 12K systems, QuantStudio 5 Systems, Integra Viaflow 96 and Integra Assist Plus" revealed "3.3 STORAGE . 3.3.1 Specimens can be stored for up to 72 hours after collection. 3.3.2 If a delay in extraction is expected, store specimens at -70 degrees Celsius or lower." Review of laboratory procedure "SOP-22 Control of Nonconformance" revealed "Downtime...If a delay is expected to exceed 48 hours, store the specimens appropriately (e.g. freeze the specimens) and notify the requesting clinician of the delay." Review of laboratory procedure "SOP-24 Sample Rejection" revealed no mention of rejection of samples due to time or storage of specimens. Review of 2021 laboratory specimen rejection logs revealed specimen order code ID: "20210217609N1" was rejected on "10/05/2021" due to "outside 72 hour window". Interview with the TS at approximately 10:55 a.m. confirmed that

	current lab procedure is that specimens are received and processed for extraction within 72 hours of collection. At approximately 11:55 a.m., the TS stated that after extraction the extracted specimens (nucleic acids) are stored frozen for up to 4 days and can be rerun up to 4 days if a retest is needed. After 4 days, the extracted specimens are discarded. During interview at approximately 2:00 p.m., the lab owner confirmed that specimens not received at the lab within 72 hours of collection are rejected and there is a process to contact the patient for recollection.
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: Based on review of the laboratory's policies and procedures and interview with the TS (technical supervisor) 3/22/22, the laboratory's policies and procedures had not been approved by the current laboratory director. Review of the laboratory's procedure manual revealed the following procedures were not signed and dated by the current director to indicate review and approval: 1. SOP-01 Good Laboratory Practice 2. SOP-02 Competency Assessment 3. SOP-04 Proficiency Testing 4. SOP-05 Referral of Specimens to Outside Labs 5. SOP-06 Post-Analytic Procedures 6. SOP-07 Pipette Calibration 7. SOP-10 CovidNow SARS-CoV-2 using KingFisher & QuantStudio 12K Systems and QuantStudio 5 Systems (2nd Revision) 8. SOP-22 Control of Nonconformances 9. SOP-23 Corrective and Preventive Actions 10. SOP-24 Sample Rejection During interview at approximately 3:50 p.m., the TS verified that the procedures were not approved by the current laboratory director.
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 the King Fisher analyzer validation records, the absence of documentation, review of manufacturer's instructions, and interview with TS (technical supervisor) and TP (testing personnel) #1 on 3/22/22, the laboratory failed to establish performance specifications for "CovidNow SARs-COV-2 Assay" tests performed on 2 of 4 King Fisher analyzers. Findings: Review of validation records revealed validation studies were performed for 2 King Fisher analyzers with serial numbers 711-8G0538 and 711-8G80420, but there was no documentation that the laboratory established performance specifications for accuracy, precision and

	reportable range for the "CovidNow SARs-COV-1 Assay" performed on the other 2 King Fisher analyzers with serial numbers 711-8G0502 and 711-8G0506. Review of the manufacturer's package insert for "CovidNow SARs-COV-2 Assay Instructions for Use" revealed this assay is "For Emergency Use Authorization (EUA) Only". Interview with TS at approximately 10:55 a.m. confirmed that the laboratory runs patient specimens on all four King Fisher analyzers located in the lab. Interview with TP#1 at approximately 5:30 p.m. confirmed that the laboratory runs patient specimens on King Fisher analyzers with serial numbers 711-8G0502 and 711-8G0506.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, review of personnel records, and interview with the TS (technical supervisor) 3/22/22, the laboratory director failed to ensure that prior to testing patient specimens, 3 of 6 testing personnel (TP #4, #5, #6), the GS (general supervisor), and the TS (technical supervisor) received appropriate training and had demonstrated they could perform all testing operations reliably to provide and report accurate test results. Findings: The laboratory's "COMPETENCY ASSESSMENT" procedure states "... 5.1 ... Procedures: Training of laboratory personnel by qualified personnel occurs prior to performance of patient testing on any new methodology, instrumentation, or procedure. Training documentation is maintained and available at all times. ... 5.3 ... Prior to starting patient testing and reporting patient results for new methods or instruments, each individual must have training and be evaluated for proper test performance. ..." Review of personnel records revealed: 1. Training records for TP #4, TP #5, and TP #6 were incomplete. a. Records for TP #4 did not include training dates on page 1 and 2 under "OVERVIEW OF PROCEDURE" and "SHADOWING". A note on the bottom of page 3 stated "Prior to Nov. 1 ... initially trained (TP #4). This was not documented. I have observed (TP #4) and signed off on her training /independently on 3/14/22." b. Records for TP #5 included a trainer signature and date for the "EXTRACTION" section of the checklist on pages 1, 2, and 3. All other sections were left blank. A note on the 3/14/22 competency evaluation signed by the TS stated "No documentation was completed for initial orientation - (TP #5) was trained by (an outside consulting company). Prior manager was present. I have observed (TP#5) recently to ensure technical skills." c. Records for TP #6 were blank on page 1, 2, AND 3 under "SHADOWING" and "INDEPENDENT" for: "Batch workbook generation and sample scanning Necessary reagents and storage location Necessary materials and storage location Instrument and station decontamination". Records for "EXTRACTION" on page 3 were also blank. A note on the bottom of page 3 signed by the TS stated "Training occurred with prior lab supervisor with no records on some training, but (TP #6) has since been observed, trained on lab techniques." 2. Training records for the GS were incomplete. There were no training dates documented for items listed on page 2 of the training document, including observation of the GS demonstrating sample extraction, reagent preparation, and data analysis. 3. There were no training records available for the TS. During interview at

	approximately 10:55 a.m., the TS stated she trained all TP or verified their training when she started, but did not document it. At approximately 12:00 p.m., the TS stated that she was trained when she started in October 2021, but her training was not documented.