Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D2023923	03/03/2022
Name of Provider or Supplier	**Street Address, City, State**	
F C Lab Lemont	807 State St, Lemont, IL	

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
D3005	FACILITIES CFR(s): 493.1101(a)(3) Molecular amplification procedures that are not contained in closed systems have a uni-directional workflow. This must include separate areas for specimen preparation, amplification and product detection, and, as applicable, reagent preparation. This STANDARD is not met as evidenced by: Based on direct observation and interview, the laboratory failed to maintain a uni-directional workflow for the laboratory developed Reverse Transcriptase (RT) Polymerase Chain Reaction (PCR) procedures used to test more than 27,050 patient specimens. Findings Include: 1. The laboratory used a laboratory developed test (LDT) procedure for RT-PCR to detect and identify SARS-CoV-2, Streptococcus Group A (Strep A), methicillin-resistant staphylococcus aureus (MRSA), and Influenza A & B. 2. On a tour of the laboratory facility on March 3, 2022 at 1:40 PM, the surveyor observed the following: -Patient specimens collected from sites were received, labeled, and reracked in room #1; -The reracked specimens were then taken to room #2, which is adjacent to room #1. In room #2, specimens were accessioned, prepped, treated, and pipetted into test plates. -The completed test plate(s) were taken through a small hallway. -Situated in this hallway were two Real-time PCR analyzers, the Applied Biosystem (ABI) 7500 & 7900HT Fast. -Past the analyzers towards the end of the hallway to the left was room#3. In this room the reagents, master mix, nucleic acid, etc. were made and added to the plate which is now ready to run. -From room#3, the plate(s) were taken back into the hallway to the ABI 7500/7900HT station where the assay was performed. -Also, at the end of the hallway adjacent to Room#3 were the breakroom area, kitchen, and exit/entrance door for personnel. 3. Direct observation of the technical supervisor on March 3, 2022 at 2:10 PM, demonstrated PCR analysis of patients' test data and it was observed that multiple personnel were passing back and forth from room#1 and 2 through the hallway to the breakroom or exit door creating a bottleneck at the PCR analyzer station. 4. Interview

	with the testing personnel on March 3, 2022, at 2:15 PM revealed that the laboratory had not performed any wipe tests to evaluate the contamination of the main specimen processing area since the unidirectional workflow was not maintained. 5. Interview with the laboratory director on March 3, 2022, at 2:15 AM confirmed more than 27,050 patients had been tested for SARS-CoV-2, MRSA, Strep Group A, and Influenza A&B while the laboratory failed to maintain a uni-direction workflow.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on direct observation, record review, lack of documentation, and interview, the laboratory failed to establish written policies and procedures to assess employees performing the Reverse Transcriptase (RT) Polymerase Chain Reaction (PCR) laboratory developed tests (LDTs) for seven of seven testing personnel (TP). Findings include: 1. The competency policy and procedures, employee files, and the Laboratory Personnel Report (CMS 209) were reviewed. 2. The laboratory used laboratory developed RT-PCR tests to detect and identify SARS-CoV-2, Streptococcus Group A (Strep A), methicillin-resistant staphylococcus aureus (MRSA), and Influenza A & B. 3. The CMS 209 reviewed listed seven TP (TP1, TP2, TP3, TP4, TP5, TP6, and TP7) performing the LDT tests. 4. Review of the competency procedure and employee files showed 7 of 7 TP were assessed on the eppendorf pipetting instrument. 5. During a tour of the laboratory facility on March 3, 2022 at 1:40 PM, the surveyor observed TP1, TP2, and TP3 receive and accession specimens, perform reagent preparation, sample extractions, PCR plate preparations, and result reporting. 6. Interview with TP1 on March 3, 2022 at 2:00 PM, described their duties in the laboratory to include, resuspension of reagents, extraction of patient specimens, accessioning patients' specimens to prepare for pipetting, test plate processing (depending on LDT method), master mix preparation and addition, running assays on the Applied Biosystem (ABI) 7500 and 7900HT Fast Real-Time PCR analyzers, analyzing the test data, and reporting patients results. 7. Further review of the competency policy and procedure revealed that the laboratory failed to include these activities and processes in their competency policy and procedures. 8. The laboratory director and TP1 confirmed the above findings on March 3, 2022, at 2:45 PM.
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 direct observation, record review, lack of documentation, and interview, the

	laboratory failed to establish written policies and procedures for specimen submission, handling, and referral procedures (D5311) for the laboratory developed Reverse Transcriptase (RT) Polymerase Chain Reaction (PCR) procedures used to detect and identify SARS-CoV-2, Streptococcus Group A(Strep A), methicillin-resistant staphylococcus aureus (MRSA), and Influenza A & B, affecting 27, 058 patients tested.
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 direct observation, record review, lack of documentation, and interview the laboratory failed to establish written policies and procedures for specimen submission, handling, and referral for four of four laboratory developed tests (LDTs) reviewed affecting 27,058 patient tests performed. Findings include: Item 1. 1. The laboratory's policies and procedures were reviewed. 2. The laboratory used a laboratory developed Reverse Transcriptase (RT) Polymerase Chain Reaction (PCR) test (LDT) to detect and identify SARS-CoV-2, Streptococcus Group A(Strep A), methicillin-resistant staphylococcus aureus (MRSA), and Influenza A & B. 3. Direct observation of testing personnel (TP2) on March 3, 2022 at 11:50 AM, demonstrated the specimen receiving process and it was observed that the patient specimens removed from the specimen bags did not have requisitions. These specimens were placed in a test tube rack and taken to a computer designated for receiving specimens. TP2 entered the name and date of birth written on the patient's tube into the laboratory Information system (LIS) which retrieved the patient's information/order. The LIS assigned the patient a number and generated a barcode label for the patient's specimen tube. 4. Interview with the laboratory director (LD) on March 3, 2022 at 11:55 AM, the LD stated that requisitions were not required for standing orders. 5. The laboratory reported 25,523 SARS-CoV-2 test results. Item 2. 6. Direct observation on March 3, 2022 at 1:40 PM, the surveyor observed TP3 enter the laboratory from the outside with a test tube rack of patient specimens contained in a plastic bag. The specimen rack removed from the plastic bag contained 26 patient specimen tubes with the barcode label already attached and no requisitions forms. Further examination of the tubes revealed 26 of 26 had no visible written identifiers. TP3 transferred the 26 specimens to another rack and took them to room#2 for PCR processing. 7. Interview with the LD on March 3, 2022 at 1:40 PM, the LD stated these patient specimens were collected at the laboratory located on 8635 Lemont Rd, Downers Grove (14D1078862). The patient information, collection, and barcoding were done at the Downers Grove laboratory and transported to the Lemont laboratory without requisitions. 8. Review of the laboratory's policies and procedures revealed the processes described in findings #3, #5, and #6 had not been included in their manuals and the laboratory failed to establish a written preanalytic policy and procedure that included and detailed the following: (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. for the SARS-CoV-2, MRSA, Strep Group A, and Influenza A&B performed in the laboratory. 9. The laboratory reported 58 RSV and Influenza A&B, 29 MRSA, and 5 Strep Grp A results. 10. The LD confirmed the above findings on March 3, 2022, at 3:35 PM and stated that the laboratory does not have a requisition form but it can be created in their computer system upon request.
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, record review, lack of documentation, and interview the laboratory's procedure manual failed to include all the applicable requirements specified in 493.1251 (b)(1) - (14) for the Reverse Transcriptase (RT) Polymerase Chain Reaction (PCR) laboratory developed tests (LDTs) performed affecting 27,058 patients tests. Findings Include: 1. The laboratory's procedures manuals, the Applied Biosystem (ABI) 7500 and 7900HT Fast Real-Time RT-PCR analyzers operator's manual, maintenance worksheets, and patients test reports were reviewed. 2. The laboratory tested patients' nasopharyngeal swabs for the detection and identification of SARS-CoV-2, Streptococcus Group A (Strep A), methicillin-resistant staphylococcus aureus (MRSA), and Influenza A & B using the RT-PCR LDT procedures. 3. The procedures manual failed to include the following requirements for the SARS-CoV-2, MRSA, Strep Group A, and Influenza A&B LTDs: *Requirements for patient preparation; storage, preservation, transportation, and processing, Specimen referral procedures and criteria for specimen acceptability and rejection. See D5300 & D5311. *Step-by-step performance of the procedure, including test calculations and interpretation of results. *Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. *Step-by-step calibration and maintenance procedures for the ABI 7500/7900HT analyzers. *Control Procedures and Interpretation of results. Direct observation on March 3, 2022 at 2:15 PM, observed the technical supervisor visually selecting suspected positive and negative SARS-CoV-2 patient specimens from the completed ABI -RT-PCR graph. The laboratory failed to include this process in the procedure. Further review revealed the laboratory failed to establish quality control criteria for acceptability and define how

	the laboratory determined and processed inconclusives, internal control failures, and re-runs for each LDT. *Pertinent literature references. *The Corrective action to take when control results fail to meet the laboratory's criteria for acceptability. *To describe the course of action to take if a test system becomes inoperable. 4. The laboratory performed 27,058 patient tests for SARS-CoV-2, MRSA, Strep A, and Influenza A&B. 5. The LD confirmed the above findings on March 3, 2022, at 3:35 PM.
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 record review, lack of documentation, and interviews, the laboratory failed to establish the performance specifications for four of four Reverse Transcriptase (RT) Polymerase Chain Reaction (PCR) laboratory developed tests (LDTs) performed affecting 27,058 patients' tests. Findings Include: Item 1. 1. The laboratory's verification records, patient test records and procedures manual were reviewed. 2. The laboratory tested patients' nasopharyngeal swabs for the detection and identification of SARS-CoV-2, Streptococcus Group A (Strep A), methicillin-resistant staphylococcus aureus (MRSA), and Influenza A & B using the RT-PCR LDT procedure. 3. The verification records and manual revealed the laboratory failed to establish and perform methods to provide evidence that, as applicable, the (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; is adequate to meet the patients' needs as determined by the laboratory director and clinical consultant for SARS-CoV-2, MRSA, Strep A and Influenza A&B detection and identification. 4. Review of the test records revealed that it could not be determined when the laboratory began implementing the SARS-CoV-2 RT-PCR LDT after they no longer performed the CDC 2019 Novel-Coronavirus (2019-nCoV) Real-Tme RT-PCR Emergency Use Authorize (EUA) test. 5. The laboratory reported 25,523 SARS-CoV-2 test results. 6. The LD confirmed the above findings on March 3, 2022, at 3:35 PM.
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 record review, lack of documentation, and interview with the laboratory director (LD), the LD failed to ensure that verification procedures were adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method used (D6086) to detect and identify SARS-CoV-2 and failed to specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing (D6107) for eight of eight laboratory personnel.
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method. This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and interview with the laboratory director (LD), the LD failed to ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method used for SARS-CoV-2 affecting 25,523 patients tests. Findings include: 1. The CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time Reverse Transcriptase Diagnostic Panel Emergency Use Authorization (EUA), the laboratory developed Real-Time Reverse-Transcriptase (RT)-Polymerase Chain Reaction (PCR) procedure and procedures manual were reviewed. 2. The laboratory was using the Real Time Applied Biosystem (ABI) 7500 & 7900HT Fast PCR analyzers for SARS-CoV-2. 3. The verification procedures and documents and the CDC 2019-nCoV RT-PCR EUA revealed the following: *The LD failed to ensure verification procedures were performed for the SARS-CoV-2 LDT when the laboratory no longer performed the 2019-nCoV EUA procedure, prior to testing patients. *The LD failed to provide how the LDT results met the performance characteristics as compared to the Food and Drug Administration (FDA)-CDC 2019-nCoV EUA, prior to testing patients. *It could not be determined when the LDT was put into use for testing patients. See D5423. 4. The LD confirmed the above findings on March 3, 2022 at 2:35 PM.
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on record review, the lack of documentation, and interview with the laboratory director (LD); the LD failed to specify, in writing, the responsibilities and duties for one of one technical supervisor (TS), one of one general supervisor (GS) and seven of

	seven testing personnel (TP) engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required, in the specialties and subspecialties Microbiology, prior to testing and reporting 27,058 patients' samples. Findings include: 1. The laboratory personnel documents, the Laboratory Personnel Report (CMS 209), and manuals were reviewed. 2. The LD failed to assign the following the duties/responsibilities, in writing: *Technical Supervisor *Testing Personnel; and *General Supervisor 3. The CMS 209 reviewed listed seven TP (TP1, TP2, TP3, TP4, TP5, TP6, and TP7) performing the LDT tests. 4. The employee files of seven of seven TP revealed the LD failed to define, in writing, the following for the TP: *The procedures each individual is authorized to perform, *The duties the TP are to perform in the preanalytic, analytic, and postanalytic phases of testing; *Whether supervision is required for specimen processing, test performance or result reporting; and *Whether supervisory or director review is required, prior to reporting patients' test results. 5. The LD confirmed the above findings on March 3, 2022 at 2:35 PM.