Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 14D0878205	**(X3) Date Survey Completed** 05/05/2022
Name of Provider or Supplier American Family Medical Center	**Street Address, City, State** 1254 Ogden Ave, Downers Grove, 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**
D0000	A Complaint and an Initial survey was completed on May 5, 2022. It was determined that Immediate Jeopardy (IJ) existed for the following condition level deficiencies: 42 C.F.R. 493.1250 Condition: Analytic systems 42 C.F.R. 493.1441 Condition: Laboratories performing high complexity testing; laboratory director
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on review of the American Association of Bioanalysis (AAB) proficiency testing (PT) reports, the Federal Individual Report 0155, and interview, the laboratory failed to successfully participate in two of three consecutive PT program events for the specialty of Hematology (D2130, D2131).

D2130	HEMATOLOGY CFR(s): 493.851(f) Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and interview, the laboratory failed to attain a satisfactory performance score for Erythrocyte Counts (RBC), Hemoglobin (Hgb), and Hematocrit (Hct) for two of three consecutive events in the specialty of Hematology. Findings include: 1. The American Association of Bioanalysis (AAB) proficiency testing (PT) documents from 2021, the Federal Report 0155, and procedures manual were reviewed. 2. The AAB-PT reports revealed the laboratory received unsuccessful PT performance in the specialty of Hematology for the analytes as listed below: HEMATOLOGY Event #3, 2021 Event #1, 2022 RBC - Score = 60% RBC = 0% Hgb - Score = 60% Hgb = 0% Hct - Score = 60% Hct = 0% 3. Review of the Federal Report 0155 showed the laboratory received for Event #1 2022 an overall score of 0% for non-participation. 4. Further review of the PT documents and PT policy showed the PT failures were noted but the laboratory failed to follow procedures and provide documented evidence the failures and non-participation score were investigated, and corrective actions implemented by the laboratory director (LD) or technical consultant (TC). 5. The LD, owner, and laboratory staff on May 5, 2022, at 3:12 PM, confirmed the above findings.
D2131	HEMATOLOGY CFR(s): 493.851(g) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and interview, the laboratory failed to attain an overall satisfactory performance score for two of three events in the specialty of Hematology. Findings include: 1. The American Association of Bioanalysis (AAB) proficiency testing (PT) documents from 2021, the Federal Report 0155, and procedures manual were reviewed. 2. The AAB-PT reports revealed the laboratory received unsuccessful PT performance in the specialty of Hematology for the analytes as listed below: HEMATOLOGY Event #3 2021- Overall Score=73% Event #1 2022 - Overall Score = 0% Leukocytes Count (WBC) - Score = 80% Erythrocyte Count (RBC) - Score = 60% Hemoglobin (Hgb) - Score = 60% Hematocrit (Hct) - Score = 60% Platelet - Score = 80% 3. Review of the Federal Report 0155 showed the laboratory received for Event #1 2022 an overall score of 0% for non-participation. 4. Further review of the PT documents and PT policy showed the PT failures were noted but the laboratory failed to follow procedures and provide documented evidence the failures and non-participation score were investigated, and corrective actions implemented by the laboratory director (LD) or technical consultant (TC). 5. The LD, owner, and laboratory staff on May 5, 2022, at 3:12 PM, confirmed the above findings.
D3031	RETENTION REQUIREMENTS

	CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and interview, the laboratory failed to retain for nine of eleven months the plate runs and patient test records for the Reverse Transcriptase (RT) Polymerase Chain Reaction (PCR) test procedure used to identify and detect SARS-CoV-2 Virus for at least 2 years, affecting 52,113 patients' results. Findings include: 1. Interview with Staff B on May 05, 2022 at 2:25 PM, the surveyor requested Staff-B to provide one plate run from the month of October 2021, December 2021, February 2022, and April 2022. The surveyor received plate runs from the month of February and April 2022, but nothing from the months selected in 2021. Staff-B stated that he did not know the location of the PCR run data for dates prior to February 2022. 2. Review of the laboratory's retention policy showed the requirement to retain all test data and patients' test records for at least two years was included in the policy. 3. The Quality Assurance (QA) records reviewed from June 2021 through January 2022 showed that record retention was not included in its procedure to be monitored. 4. Further review of the QA records revealed that 52,113 patients tests were tested and reported from June 2021 through January 2022. 5. The owner, laboratory director and staff on May 5, 2022, at 3:12 PM, confirmed the above findings.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and interview, the laboratory failed to document four of four proficiency testing (PT) events reviewed for Hematology and Virology. Findings Include: 1. Review of American Association of Bioanalysis (AAB) PT records from event 3, 2021 through event 1, 2022 showed that the laboratory failed to document the review of the following events: Events 3, 2021 & Event 1, 2022 in Hematology. See D2016, D2130 and D2131. Events 3, 2021 & Event 1, 2022 in Virology 2. The owner, laboratory director and staff on May 5, 2022, at 3:12 PM, confirmed the above findings.
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 direct observations, record review, Emergency Use Authorization (EUA) and interviews, the laboratory failed to validate the performance characteristics of the Genefinder COVID-19 Plus RealAmp EUA Reverse Transcriptase (RT) Polymerase Chain Reaction (PCR) (D5421) test; failed to establish and document performance specifications for the laboratory developed test (LDT) RT-PCR procedures (D5423) used to detect and identify the SARS-CoV-2 virus; and failed to document the lot numbers and expiration dates of the controls, kits, and reagents used in these test systems (D5471) to ensure reliable and accurate test results, affecting 86,600 patients' tests.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on direct observation, record review, lack of documentation, and interview, the laboratory failed to demonstrate that it could obtain the performance characteristics established by the Genefinder Emergency Use Authorization (EUA) Reverse Transcriptase (RT) Polymerase Chain Reaction (PCR) test procedures used to detect and identify the SARS-CoV-2 virus for five of five BioRad C1000 Touch Thermocyclers before reporting patients results, affecting 86,600 tests. Findings: 1. Direct observation on May 5, 2022, at 12:05 PM, the surveyor observed five BioRad Thermocyclers: a. Two C1000 Touch -CFX96-well (No Serial number (S/N)) b. C1000 Touch -CFX96-well (S/N #CT051678) c. C1000 Touch -CFX96-well (S/N #CT051662) d. C1000 Touch -CFX384-well (No S/N) 2. The Genefinder COVID-19 Plus RealAmp Kit EUA Information for Use (IFU) manual, PCR validation test documents, the laboratory personnel reports (CMS-209), patient results, and procedures manual were reviewed. 3. The laboratory used the Genefinder EUA and the BioRad C1000 Touch thermocyclers to detect and identify SARS-CoV-2 virus in nasopharyngeal swabs. 4. The Genefinder PCR test data revealed that the verification procedures were performed by personnel not listed on the CMS-209 and were approved by an unqualified laboratory director in June 11, 2021 using a QuantStudio 12 Flex PCR analyzer (S/N-285881950). 5. The laboratory failed to provide any documentation that showed the Genefinder EUA procedures were verified using the five C1000 Touch BioRad thermocyclers, approved by the current laboratory director hired who was hired on March 29, 2022, and implemented by the current laboratory testing personnel. 6. The monthly QA reports revealed 86,600 patients' tests were reported from June 2021 through April 2022. 7. The laboratory director, owner, and laboratory staff on May 5, 2022, at 3:12 PM, confirmed the above findings.
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 direct observations, records review, lack of documentation, and interviews; the laboratory failed to establish and document the performance specifications of the modified Genefinder COVID-19 Plus RealAmp Kit Emergency Use Authorization (EUA) Reverse Transcriptase (RT) Polymerase Chain Reaction (PCR) test procedure for five of five BioRad C1000 Touch Thermocyclers used to detect the SARS-CoV-2 virus to ensure accurate and reliable results prior to testing patients, affecting 61,009 patients' test results. Findings Include: 1. 1. Direct observation on May 5, 2022, at 12:05 PM, the surveyor observed five BioRad Thermocyclers: a. Two C1000 Touch -CFX96-well (No Serial number (S/N)) b. C1000 Touch -CFX96-well (S/N #CT051678) c. C1000 Touch -CFX96-well (S/N #CT051662) d. C1000 Touch -CFX384-well (No S/N) 2. Interview with Staff B, on May 05, 2022 at 12:10 PM, during a tour of the laboratory, it was stated that the laboratory used the GeneFinder EUA but no longer performed the extraction process as instructed in the EUA's procedure. 3. The Genefinder COVID-19 Plus RealAmp Kit EUA/Instructions for Use (IFU) manual, the laboratory's test data and validation records, procedures manuals, and quality assurance (QA) reports from January 2022 to April 2022 were reviewed. 4. The test data and validation records revealed the procedural change to "No Extraction" was implemented and signed by an unqualified technical supervisor (See D6108 & D6111) on 12/29/2021 without any written evidence of approval by a qualified laboratory director. 5. Further review of the RT-PCR test data showed the validation testing was performed by personnel not listed on the CMS-209 and they failed to perform the following performance studies for five of five when the Genefinder EUA specimen processing procedures were no longer followed: a. Accuracy. b. Precision. c. Analytical sensitivity. d. Analytical specificity to include interfering substances. e. Reportable range of test results for the test system. f. Reference intervals (normal values). g. Any other performance characteristic required for test performance. 6. 61,009 patients' specimens were tested with the extraction-less RT-PCR procedure during the time reviewed. 7. The laboratory director, owner, and laboratory staff on May 5, 2022, at 3:12 PM, confirmed the above findings.
D5471	CONTROL PROCEDURES CFR(s): 493.1256(e)(1)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. (g) The laboratory must document all control procedures performed.

	This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and interview, the laboratory failed to document each kit's lot numbers, expiration dates, and shipment of reagents when opened or prepared for positive or negative reactivity (amplification) each day the Genefinder Emergency Use Authorization (EUA) and the laboratory developed (LDT) SARS-CoV-2 Reverse Transcriptase (RT) Polymerase Chain Reactions (PCR) tests were performed for two of two PCR runs reviewed. Findings: 1. The laboratory's procedure manual, Genefinder COVID-19 Plus RealAmp kit EUA/Information for Use (IFU), the LDT PCR plate runs on the BioRad Thermocycler (Instrument #1, Serial Number (S/N): CT046195) from February 17, 2022 and the BioRad Thermocycler (Instrument #3 S/N: CT051682) from April 7, 2022, and quality assurance (QA) monthly reports from June 2021 through April 2022 were reviewed. 2. The laboratory used RT-PCR analysis to detect and identify the presence of SARS-CoV-2 Ribonucleic Acid (RNA) in patients' nasopharyngeal swabs. 3. The Genefinder EUA/IFU procedures provided lists of reagents and controls needed to perform the PCR test. 4. The modified Genefinder LDT-PCR plate runs selected revealed that for two of two days of testing the laboratory failed to document the lot numbers, expiration dates, when opened or prepared, the controls, kits and reagents used in their runs, affecting 109 patients' results. 5. Interview with Staff B, on May 05, 2022 at 2: 25 PM, the surveyor requested Staff-B to provide one plate run from the month of October 2021 and one plate run from the month of December 2021 when the laboratory was performing the unmodified Genefinder EUA. Staff-B stated that he did not know the location of the PCR run data for dates prior to February 2022. See D3031. 6. The laboratory manual failed to include the requirement and establish a method to document each day of testing the information listed in finding number 4 for controls, kits, and reagents used to perform the RT-PCR tests. 7. The QA reports showed 86,600 patient specimens were tested during the period reviewed. 8. The laboratory director, owner, and laboratory staff on May 5, 2022, at 3:12 PM, confirmed the above findings.
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 direct observation, record review, the Laboratory Personnel Report (CMS-209), and interview; the laboratory director (LD) failed to ensure that the modified Genefinder Reverse Transcriptase (RT) Polymerase Chain Reaction (PCR) procedures used for SARS-CoV-2 detection and identification provide quality laboratory services for all aspects of test performance (D6082); failed to ensure that verification procedures for the Genefinder COVID-19 Plus RealAmp Kit Emergency Use Authorized (EUA) were performed and acceptable (D6086); and failed to ensure the laboratory employed a qualified technical supervisor and general supervisor (See D6101), affecting 86,600 patients' results.
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 record review and interview, the laboratory director (LD) failed to ensure that the modified Genefinder laboratory developed test (LDT) used for SARS-CoV-2 detection and identification provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing, affecting 61,009 patients' tests. Findings: 1. The Genefinder COVID-19 Plus RealAmp Kit Instructions for Use (IFU) and Emergency Use Authorization (EUA), the laboratory's test data and validation records, procedures manuals, and quality assurance (QA) reports from January 2022 through April 2022 were reviewed. 2. The laboratory modified the Genefinder EUA to perform the Reverse Transcriptase (RT) Polymerase Chain Reaction (PCR) procedures to detect and identify SARS-CoV-2 in patients' nasopharyngeal specimens. See D5423. 3. The procedures manuals and Genefinder EUA revealed the LD failed to ensure the laboratory performed an approved SARS-CoV-2 PCR procedure (Genefinder EUA) and defined performance specifications for the modified SARS-CoV-2 PCR procedure (Extraction-less Genefinder COVID-19 Plus RealAmp kit). See D5421 & D5423. 4. The laboratory reported 61,009 patients results during the time period reviewed. 5. The LD, Owner and Staff-SP confirmed the above findings on May 5, 2022 at 3:15 PM.
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 and interview; the laboratory director (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 two of two SARS-CoV-2 Reverse Transcriptase (RT) Polymerase Chain Reaction (PCR) test procedures, affecting 61,009 patients results. Findings include: 1. The Emergency Use Authorization (EUA) and Information for Use (IFU) for Genefinder COVID-19 Plus RealAmp Kit, the laboratory developed test (LDT) using the Genefinder EUA kit, PCR test data, procedures manual, and patients' reports were reviewed. 2. The laboratory performed the Genefinder EUA and LDT-PCR to detect and identify SARS-CoV-2 virus in nasopharyngeal swabs. 3. The verification and test data revealed the following: *The Genefinder EUA validation procedure was approved by an unqualified LD (Staff-G) in June 2021. *The change in specimen processing (no extraction) was implemented by Staff-G in December 29, 2021. *A qualified LD was hired on March 29, 2022. *The laboratory began testing and reporting SARS-CoV-2 RT-PCR results in June of 2021. *The laboratory continued to test and report RT-PCR during the period when the LD was unqualified and when the LD position was vacant. *The new LD failed to review all previous and current validation records, verification procedures, proficiency testing performances, staff competency and qualifications,

	and laboratory policies and procedures to ensure they met criteria necessary to provide accurate and reliable testing. See D6082, D6101, D6108, D6111, D6141, and D6143. 4. The laboratory reported 61,009 patients results during the time period reviewed. 5. The LD, Owner and Staff-SP confirmed the above findings on May 5, 2022 at 3:15 PM.
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 record review and interview, the laboratory director (LD) failed to employ employees with the appropriate education and either experience or training to provide appropriate consultation and properly supervise in accordance with the personnel responsibilities prior to testing patients' specimens, affecting four of five testing personnel (TP). Findings include: 1. The employee files, the Laboratory Personnel Report (CMS 209), and patients' reports were reviewed. 2. The CMS 209 listed five TP, one technical supervisor (TS) and one general supervisor (GS) in the laboratory performing the Real-Time Reverse Transcriptase (RT) Polymerase Chain Reaction (PCR) GeneFinder SARS-CoV-2 procedures. 3. The LD failed to ensure the laboratory had a qualified TS and GS. See D6108, D6111, D6141, and D6143. 4. Further review of the personnel records showed four of five TP were trained and assessed by unqualified personnel. 5. The LD failed to ensure five of five TP were evaluated as competent and authorized to perform RT-PCR testing. 6. 86,600 patients' tests were reported during the time reviewed. 7. The LD, owner, and laboratory staff on May 5, 2022, at 3:12 PM, confirmed the above findings.
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 records review, the laboratory personnel report (CMS-209), and interview, one of one technical supervisors (TS) identified on the CMS-209 failed to meet the qualification requirements as a TS (D6111) for the Real-Time Reverse Transcriptase (RT) Polymerase Chain Reaction (PCR) procedures performed to detect and identify SARS-CoV-2 virus, affecting 86,600 patients' tests.
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 records review, the laboratory personnel report (CMS-209), and interview, one of one technical supervisors (TS) identified on the CMS-209 failed to meet the qualification requirements as a TS for the Real-Time Reverse Transcriptase (RT) Polymerase Chain Reaction (PCR) procedures performed to detect and identify SARS-CoV-2 virus, affecting 86,600 patients' tests. Findings Include: 1. The employee files, CMS-209, monthly Quality Assurance (QA) reports from June 2021 through April 2022, and procedures manual were reviewed. 2. The laboratory performed RT-PCR using the GeneFinder SARS-CoV-2 Assay procedures. 3. The CMS-209 listed Staff-B as TS. 4. The employee's file for Staff-B revealed the following: *Received Bachelor of Science in Biology on May 2017 and Master of Arts in Biomedical Sciences on May 2021. *Hired as TS on May 2021. *Received training at laboratory to perform GeneFinder SARS-Cov-2 Assay on July 26, 2021. 5. Staff-B failed to have two years of CLIA laboratory experience in Virology. 6. The monthly QA reports revealed 86,600 patients' tests were reported during the period reviewed. 7. The laboratory director, owner, and laboratory staff on May 5, 2022, at 3:12PM, confirmed the above findings.
D6141	GENERAL SUPERVISOR CFR(s): 493.1459 The laboratory must have one or more general supervisors who are qualified under 493.1461 of this subpart to provide general supervision in accordance with 493.1463 of this subpart. This CONDITION is not met as evidenced by: Based on records review, the laboratory personnel report (CMS-209), and interview, one of one general supervisors (GS) identified on the CMS-209 failed to meet the qualification requirements as a GS (D6143) for the Real-Time Reverse Transcriptase (RT) Polymerase Chain Reaction (PCR) procedures performed to detect and identify SARS-CoV-2 virus, affecting 86,600 patients' tests.
D6143	GENERAL SUPERVISOR QUALIFICATIONS CFR(s): 493.1461 (a) The general supervisor must possess a current license issued by the State in which

the laboratory is located, if such licensing is required; and (b) The general supervisor must be qualified as a-- (b)(1) Laboratory director under 493.1443; or (b)(2) Technical supervisor under 493.1449. (c) If the requirements of paragraph (b)(1) or paragraph (b)(2) of this section are not met, the individual functioning as the general supervisor must-- (c)(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 or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; and (c)(1)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing; or (c)(2)(i) Qualify as testing personnel under 493.1489(b)(2); and (c)(2)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing; or (c)(3)(i) Except as specified in paragraph (3)(ii) of this section, have previously qualified as a general supervisor under 493.1462 on or before February 28, 1992. (c)(3)(ii) Exception. An individual who achieved a satisfactory grade in a proficiency examination for technologist given by HHS between March 1, 1986 and December 31, 1987, qualifies as a general supervisor if he or she meets the requirements of 493. 1462 on or before January 1, 1994. (c)(4) On or before September 1, 1992, have served as a general supervisor of high complexity testing and as of April 24, 1995-- (c)(4)(i) Meet one of the following requirements: (c)(4)(i)(A) Have graduated from a medical laboratory or clinical laboratory training program approved or accredited by the Accrediting Bureau of Health Education Schools (ABHES), the Commission on Allied Health Education Accreditation (CAHEA), or other organization approved by HHS. (c)(4)(i)(B) Be a high school graduate or equivalent and have successfully completed an official U.S. military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician). (c)(4)(ii) Have at least 2 years of clinical laboratory training, or experience, or both, in high complexity testing; or (c)(5) On or before September 1, 1992, have served as a general supervisor of high complexity testing and-- (c)(5)(i) Be a high school graduate or equivalent; and (c)(5)(ii) Have had at least 10 years of laboratory training or experience, or both, in high complexity testing, including at least 6 years of supervisory experience between September 1, 1982 and September 1, 1992. (d) For blood gas analysis, the individual providing general supervision must-- (d)(1) Be qualified under 493.1461(b)(1) or (2), or 493.1461(c); or (d)(2)(i) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; and (d)(2)(ii) Have at least one year of laboratory training or experience, or both, in blood gas analysis; or (d)(3)(i) Have earned an associate degree related to pulmonary function from an accredited institution; and (d)(3)(ii) Have at least two years of training or experience, or both in blood gas analysis. (e) The general supervisor requirement is met in histopathology, oral pathology, dermatopathology, and ophthalmic pathology because all tests and examinations, must be performed: (e)(1) In histopathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(l)(1); (e)(2) In dermatopathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(l) or (2); (e)(3) In ophthalmic pathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(1)(3); and (e)(4) In oral pathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(m).

This STANDARD is not met as evidenced by:
Based on records review, the laboratory personnel report (CMS-209), and interview, one of one general supervisors (GS) identified on the CMS-209 failed to meet the

	qualification requirements as a GS (D6143) for the Real-Time Reverse Transcriptase (RT) Polymerase Chain Reaction (PCR) procedures performed to detect and identify SARS-CoV-2 virus, affecting 86,600 patients' tests. Findings Include: 1. The employee files, CMS-209, and procedures manual were reviewed. 2. The laboratory performed RT-PCR using the GeneFinder SARS-CoV-2 Assay procedures. 3. The CMS-209 listed Staff-B as GS. 4. The employee's file for Staff-B revealed the following: *Received Bachelor of Science in Biology on May 2017 and Master of Arts in Biomedical Sciences on May 2021. *Hired as GS and technical supervisor in May 2021 by the owner. *Received training at laboratory to perform GeneFinder SARS-Cov-2 Assay on July 26, 2021. *No documented evidence the laboratory director authorized Staff-B to fulfill the duties of GS. 5. Staff-B failed to have one years of CLIA laboratory experience in Virology. 6. The monthly QA reports revealed 86,600 patients' tests were reported during the period reviewed. 7. The laboratory director, owner, and laboratory staff on May 5, 2022, at 3:12 PM, confirmed the above findings.