Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2192601	09/17/2021
Name of Provider or Supplier	**Street Address, City, State**	
Toci Labs Llc	2425 E Commercial Blvd, Ste 401, Fort Lauderdale, FL	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	A complaint survey 2021011192, was conducted on 09/08/2021-09/17/2021 at Genome LLC. The laboratory was not in compliance with 42 CFR Part 493, Requirements for Laboratories. Based on the survey findings an Immediate Jeopardy situation was identified and the laboratory was notified of the Immediate Jeopardy on 09/15/2021 at 11:28 AM. Based on record review, observation and interview, the laboratory failed to complete a validation for interfering substances, COVID-19 specimen media storage, and instrument use with the laboratory developed test COVID-19 Polymerase chain reaction (PCR) test called the COV-19 Genome Test (C19GT) before beginning patient testing from 09/24/2020 to 09/17/2021. The laboratory failed to complete a validation for Human SARS-CoV-2 Spike (trimer) Ig Total ELISA before testing COVID-19 patients from 07/01/2021 to 09/11/2021. (D5423) The following conditions were cited: D5400 -Analytic Systems D6076-Laboratory Director D6108 -Laboratory Technical Supervisor D6141-General Supervisor
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 review of Evaluation of Competency GEN-006 Policy, CMS 209 Laboratory Personnel Report, personnel records and interview, the laboratory failed to follow their Evaluation of Competency Policy from 12/15/2020 to present. Findings included: - Review of CMS 209 Laboratory Personnel Report dated and signed by the Laboratory Director (LD) on 09/08/2021 revealed that the Technical Supervisor (TS), General Supervisor (GS) and Testing Personnel (TP) was the same person. -Review of

	Laboratory Policy GEN-006 revealed that it stated "the competency of the personnel is assessed at, but not limited to the following periods: Initial Employment, Conclusion of the 3 months introductory period, 6 months after the initial employment, annually thereafter". -Review of personnel competency records revealed one Competency Evaluation for TP signed and dated by the TP on 12/15/2020 and signed by the LD but not dated; this evaluation was marked as Annual. There were no records of other competencies found for TP. -During an interview on 09/09/2021 at 1: 00 PM with TP, he confirmed that this was his competency evaluation as TP.
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 observation and record review, the laboratory failed to maintain the required storage temperatures for COVID-19 reagents and specimens in a refrigerator and three freezers from 12/01/2020 to 07/21/2021.(see D5413) Based on record review, observation and interview, the laboratory failed to complete a validation for interfering substances, COVID-19 specimen media storage, and instrument use with the laboratory developed test COVID-19 Polymerase chain reaction (PCR) test called the COV-19 Genome Test (C19GT) before beginning patient testing from 09/24/2020 to 09/17/2021. The laboratory failed to complete a validation for Human SARS-CoV-2 Spike (trimer) Ig Total ELISA before testing COVID-19 patients from 07/01/2021 to 09/11/2021.(see D5423) Based on observation and interview, the laboratory failed to validate multiple control procedures for determining positive and negative results listed in their unvalidated laboratory developed C19GT procedure from 09/11/2020 to 09/17/2021. (see D5425) Based on record review and interview, the laboratory Quality Assessment Plan (QA) failed to identify and correct the deficiencies of the unvalidated COV-19 Genome Test (C19GT) test in use from 09/11/2020 to 09/17 /2021 and the improper storage of reagents and samples for COVID-19 from 12/01 /2020 to 07/21/2021. (see D5791)
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on observation and record review, the laboratory failed to maintain the required

	storage temperatures for COVID-19 reagents and specimens in a refrigerator and three freezers from 12/01/2020 to 07/21/2021. Findings included : An observation of Storage Room on 09/08/2021 at 12:50 PM revealed General Electric Company (GE) Refrigerator, Thermo Scientific freezer (Reach-in Freezer), Omcan Deep Freezer (Flip-top freezer) and Bio-freezer in the room. The Thermo Scientific Freezer contained the 2019-nCov CDC EUA Kits and Prime Direct Probe RT-qPCR Mixes. The storage temperature requirement for 2019-nCov CDC EUA Kits and Prime Direct Probe RT-qPCR Mixes are -20 degree Celsius (C). The GE refrigerator contained Bioflex MegaBio plus Virus DNA/RNA Purification II Kits. The storage temperature requirement for Bioflex MegaBio plus Virus DNA/RNA Purification II Kits is 2-8 C. The Omcan Freezer temperature storage requirement for COVID-19 specimens was -20 C. Bio-freezer storage requirement for positive COVID-19 specimens was -80 C. Review 2020-2021 Temperature Logs revealed the Reach-In Freezer temperature requirement listed was -20 C. Reach-In Freezer temperature logs had 187 days of temperatures documented above -20 C from 12/01/2020 to 07/21/2021.The GE Refrigerator had no written required temperature range in the log sheet. GE Refrigerator temperature logs had 90 days of temperatures documented below 2-8 C from 12/01/2020 to 07/21/2021. The Flip Top temperature requirement listed was -20 C. The Flip Top temperature logs had 187 days of temperatures documented above -20 C from 12/01/2020 to 07/21/2021. The Bio-Freezer temperature requirement listed was -80 C. The Bio-Freezer temperature logs had 187 days of temperatures documented below -80 C from 12/01/2020 to 07/21/2021.
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, observation and interview, the laboratory failed to complete a validation for interfering substances, COVID-19 specimen media storage, and instrument use with the laboratory developed test COVID-19 Polymerase chain reaction (PCR) test called the COV-19 Genome Test (C19GT) before beginning patient testing from 09/11/2020 to 09/17/2021. The laboratory failed to complete a validation for Human SARS-CoV-2 Spike (trimer) Ig Total ELISA before testing COVID-19 patients from 07/01/2021 to 09/11/2021. Findings included: Review of Laboratory Developed Test The COV-19 Genome Test (C19GT) Procedure revealed that the C19GT method combines three The Food and Drug Adminstration (FDA) approved COVID-19 Emergency Use Authorization (EUA) COV-19 IDx assay, Coronavirus Disease 2019(COVD-19) Real-time RT -PCR Panel Primers and Probes and Saliva Direct. The procedure does not have a section for interfering substances. The specimen collection section states " Samples will be collected using the Medschenker Accuswab and placed into the Medschenker Smart transport media 1.5

ml vial containing 2% phosphate buffer solution ,100ug /ml gentamicin 0.5ug/ml amphotericin B and transported or stored at -20 Celsius (C) in a Acutemp HemaCool Portable Storage Freezer." The two instruments used in the procedure to perform the real-time q-PCR are Roche Lightcyler 480 and Roche Lightcyler 480 II. Review of FDA Database for COVID-19 EUA approval revealed that C19GT was not listed on the website as reviewed by the FDA. Review of the Director of Services procedure revealed " The methods are molecular diagnostic using real-time polymerase Chain reaction (PCR) and reverse transcription Realtime PCR (RT-PCR). Nasopharyngeal swabs or anterior nasal swabs must be immediately submerged into viral transport media contained in the provided collection vial upon collection. Room temperature vials must be received at Genome lab within 24 hours of collection . Upon receipt Genome will heat vortex vial and transfer media into a sterile nuclease free Eppendorf tube for analysis and storage at -20 degrees Celsius within 36 hours of collection." Review of MedSchenker Smart Transportation medium(STM) package insert revealed "storage of media at -20C is less than satisfactory than storage at 4 C or -70C and can result in loss. MedSchenker STM system was able to maintain the viability of the following organisms for at least 48 hours at both room temperature (20-25C) and in the refrigerator (2-8C) under the test conditions described above." Review of C19GT validation revealed there was no documentation of a validation for interfering substances.There was no documenation of a validation for transportation and storage of MedSchenker Smart Transportation medium at -20 degrees Celsius (C) before testing. There was no documentation for Roche Lightcycle 480 and Lightcycle 480 II instruments with serial numbers to determine which instrument was used in the validation or comparison method. The laboratory director signed validation on 11/24 /2020. Review of instrument purchasing record revealed no documentation of purchase dates for Roche Lightcycle 480 and Lightcycle 480 II. During an interview on 09/08/2021 at 3:16 PM with the molecular technologist, he stated that he would provide the information for when the two PCR instruments were purchased for use. The documents were never sent as of 9/15/2021. Review of Lightcycler 480 Software reports revealed no serial numbers to identify the Roche Lightcycle 480 or Lightcycle 480 II during testing. An observation of PCR Reading Room on 9/08/2021 at 12:42 PM revealed Roche Lightcycle 480 and Lightcycle 480 II instruments in use for Covid-19 PCR testing with C19GT kits. There was no display on both of the Roche instruments stating not in use for Covid-19 PCR testing. During an interview on 09/09 /2021 at 3:17 PM, the molecular technologist stated 9,750 patients were tested by LDT C19GT from 09/11/2020 to 09/17/2021. During an interview on 09/13/2021 at 5: 28 PM, the molecular technologist stated " Samples from our partnering urgent cares are transported and received at room temperature. Any samples to be run the following day are stored at -20C." Review of the Human SARS-CoV-2 Spike (trimer) Ig Total ELISA stated "The Human SARS-CoV-2 Spike (trimer) Ig Total ELISA Kit is a solid phase sandwich Enzyme Linked Immunosorbent Assay (ELISA)designed to detect and quantify the level of Human SARS-CoV-2 Ig total in serum and plasma. The kit is for research use only not for use in diagnostic procedures." Review of the Human SARS-CoV-2 Spike (trimer) Ig Total ELISA Validation revealed no documentation of the performance of a validation from 07/01/2021 to 09/11/2021 to test for COVID-19 antibodies total Ig using the Human SARS-CoV-2 Spike (trimer) Ig Total ELISA Kit. Review of Genome COVID-19 antibody patient reports revealed the following: 1. Patient #1A specimen was collected on 09/02/2021 and reported 09 /08/2021 as positive for COVID-19 antibodies. 2. Patient #2B specimen was collected on 07/27/2021 and reported 08/19/2021 as positive for COVID-19 antibodies. 3. Patient #3C specimen was collected on 08/24/2021 and reported 09/08/2021 as positive for COVID-19 antibodies. 4. Patient #4D specimen was collected on 07/23 /2021 and reported 08/06/2021 as negative for COVID-19 antibodies. Review of

	Reference Laboratory report revealed the following for COVID-19 antibody patients tested: 1. Patient #1A specimen was collected on 09/10/2021 and reported 09/10/2021 as positive for COVID-19 antibodies. 2. Patient #2B specimen was collected on 09/10 /2021 and reported 09/10/2021 as positive for COVID-19 antibodies. 3. Patient #3C specimen was collected on 09/10/2021 and reported 09/10/2021 as positive for COVID-19 antibodies. 4. Patient #4D specimen was collected on 09/10/2021 and reported 09/10/2021 as negative for COVID-19 antibodies. During an interview on 09 /09/2021 at 3:16 PM, the molecular technologist stated the lab was working on a validation for Human SARS-CoV-2 Spike (trimer) Ig Total ELISA and patients were reported by the reference lab first before patient testing. There was no documenation of a vaildation. He also stated four patients were tested with Human SARS-CoV-2 Spike (trimer) Ig Total ELISA. During an interview on 09/13/2021 at 5:27 PM, the molecular technologist stated " Reference lab has performed the Elisa tests on those four patients."
D5425	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(3) The laboratory must determine the test system's calibration procedures and control procedures based upon the performance specifications verified or established under paragraph (b)(1) or (b)(2) of this section. This STANDARD is not met as evidenced by: Based on observation and interview, the laboratory failed to validate multiple control procedures for determining positive and negative results listed in their unvalidated laboratory developed COV-19 Genome Test (C19GT) procedure from 09/11/2020 to 09/17/2021. Findings included: Review of Laboratory Developed Test The COV-19 Genome Test (C19GT) (Genome,LLC) procedure stated "Monoplexing Control Wells the positive control contained Prime Direct 10 ul, N1 546nm Primer-Probe 1.5 ul, 3ul Plasmid and 5.5 ul H2O. The negative control contained Prime Direct 10 ul, hRP30 546nm Primer-Probe 1.5 ul and 8.5 ul Water. Multiplexing Wells the positive control contained Prime Direct 10ul, N1 546nm Primer-Probe 1.5 ul, hRP30 546nm Primer-Probe 1.5 ul, 3 ul N 1 Plasmid and 4 ul Water. The negative control contained Prime Direct 10 ul, N1 546nm Primer-Probe 1.5 ul, hRP30 546nm Primer-Probe 1.5 ul and 7 ul Water." Review of Validation Method Procedure stated " The laboratory's verification includes written quality control procedures for each new test system being validated. These will include the range of quality control values, the frequency of testing and adherence to recommendations of the manufacturer. Changes in Quality control performance due to environmental conditions or variances in operator performances over time are monitored and documented." Review of C19GT Validation revealed the validation lacked documentation if the control method was monoplexing or multiplexing. The validation was signed by the laboratory director on 09/24/2020. Review of C19GT plate maps revealed the placement of negative and positive controls lacked documentation of which control set was used (monoplexing or multiplexing) from 9/11/2020 to 09/17/2021. During an interview on 09/09/2021 at 3:17 PM, the molecular technologist stated 9,750 patients were tested by LDT C19GT from 09/11/2020 to 09/17/2021. During an interview on 09/09/2021 at 3:20 PM, the molecular technologist did not confirm which method was used during Ct-value explanation.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c)

	(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory Quality Assessment Plan (QA) failed to identify and correct the deficiencies of the unvalidated COV-19 Genome Test (C19GT) test in use from 09/11/2020 to 09/17/2021 and the improper storage of reagents and samples for COVID-19 from 12/01/2020 to 07/21/2021. Findings included: -Review of Quality Assessment Plan stated " Method of Review - Review the current plan to determine if the monitors, frequency ,and method of the review have been made effective in identifying and correcting problems in a timely manner. Adjustments or modification to the plan are made as determined necessary by the laboratory directory and testing staff." -The QA failed to correct that the laboratory tested patients with an unvalidated C19GT test for COVID-19. Refer to D5423. -The QA failed to correct control procedures for determining positive and negative results listed the unvalidated C19GT procedure. Refer to D5425 -The improper storage of COVID-19 specimen and reagents. Refer to D5413.
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, observation and interview, the laboratory director failed to ensure the laboratory completed the validation for the laboratory developed test COVID-19 Polymerase chain reaction (PCR) test called the COV-19 Genome Test (C19GT) and Human SARS-CoV-2 Spike (trimer) Ig Total ELISA before testing COVID-19 patients. (see D6086) Based on review of CMS Laboratory personnel Report 209, personnel records, and interview, the Laboratory Director failed to employ laboratory personnel with experience/training to accurately perform and report SARS-Cov-2 tests results.(see D6101)
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, observation and interview, the laboratory director failed to ensure the laboratory completed the validation for the laboratory developed test COVID-19 Polymerase chain reaction (PCR) test called the COV-19 Genome Test (C19GT) and Human SARS-CoV-2 Spike (trimer) Ig Total ELISA before testing

	COVID-19 patients. Findings included: Refer to D5423 -Based on record review, observation and interview, the laboratory failed to complete a validation for interfering substances, COVID-19 specimen media storage, and instrument use with the laboratory developed test COVID-19 Polymerase chain reaction (PCR) test called the COV-19 Genome Test (C19GT) before beginning patient testing from 09/24/2020 to 09/17/2021. The laboratory failed to complete a validation for Human SARS-CoV-2 Spike (trimer) Ig Total ELISA before testing COVID-19 patients from 07/01/2021 to 09/11/2021. During an interview on 09/16/2021 at 9:00 AM, the molecular techonologist confirmed the laboratory director should have reviewed the vaildation before patient testing.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on record review and interview, the Laboratory Director (LD) failed to ensure the quality assessment plan corrected the laboratory deficiencies. Refer to D5791
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 review of CMS Laboratory personnel Report 209, personnel records, and interview, the Laboratory Director failed to employ laboratory personnel with experience/training to accurately perform and report SARS-Cov-2 tests results. Findings included: - Technical Supervisor and General Supervisor without Supervisor license from Florida Department of Health (FDOH). Refer to D6111 and D6143. - Testing personnel performed SARS-Cov-2 tests prior to have Florida License from the FDOH. Refer to D6170
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 record review and interview, the laboratory failed to have a qualified Technical Supervisor from 11/20/2020 to 08/11/2021. Refer to D6111.

D6111	TECHNICAL SUPERVISOR QUALIFICATIONS CFR(s): 493.1449 (a) The technical supervisor must possess a current license issued by the State in which the laboratory is located, if such licensing is required; and (b) The laboratory may perform anatomic and clinical laboratory procedures and tests in all specialties and subspecialties of services except histocompatibility and clinical cytogenetics services provided the individual functioning as the technical supervisor-- (b)(1) Is a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(2) Is certified in both anatomic and clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or Possesses qualifications that are equivalent to those required for such certification. (c) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of bacteriology, the individual functioning as the technical supervisor must-- (c)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (c)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (c)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (c)(2)(ii) Have at least one year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of bacteriology; or (c)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (c)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of bacteriology; or (c)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (c)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of bacteriology; or (c)(5)(i) Have earned a bachelor's degree in a chemical, physical, or biological science or medical technology from an accredited institution; and (c)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of bacteriology. (d) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of mycobacteriology, the individual functioning as the technical supervisor must-- (d)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (d)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (d)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor or podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (d)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycobacteriology; or (d)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited

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

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

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

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

American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (m)(2) Be certified in oral pathology by the American Board of Oral Pathology or possess qualifications for such certification; or (m)(3) An individual qualified under 493.1449(b) or paragraph (m)(1) or (2) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraphs (b) or (m)(1) or (2) of this section, the responsibility for examination and interpretation of oral pathology specimens. (n) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of radiobioassay, the individual functioning as the technical supervisor must-- (n)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (n)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (n)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (n)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing for the specialty of radiobioassay; or (n)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (n)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of radiobioassay; or (n)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (n)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing for the specialty of radiobioassay; or (n)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (n)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing for the specialty of radiobioassay. (o) If the laboratory performs tests in the specialty of histocompatibility, the individual functioning as the technical supervisor must either-- (o)(1)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (o)(1)(ii) Have training or experience that meets one of the following requirements: (o)(1)(ii)(A) Have 4 years of laboratory training or experience, or both, within the specialty of histocompatibility; or (o)(1)(ii)(B)(1) Have 2 years of laboratory training or experience, or both, in the specialty of general immunology; and (o)(1)(ii)(B)(2) Have 2 years of laboratory training or experience, or both, in the specialty of histocompatibility; or (o)(2)(i) Have an earned doctoral degree in a biological or clinical laboratory science from an accredited institution; and (o)(2)(ii) Have training or experience that meets one of the following requirements: (o)(2)(ii)(A) Have 4 years of laboratory training or experience, or both, within the specialty of histocompatibility; or (o)(2)(ii)(B)(1) Have 2 years of laboratory training or experience, or both, in the specialty of general immunology; and (o)(2)(ii)(B)(2) Have 2 years of laboratory training or experience, or both, in the specialty of histocompatibility. (p) If the laboratory performs tests in the specialty of clinical cytogenetics, the individual functioning as the technical supervisor must-- (p)(1)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (p)(1)(ii) Have 4 years of training or experience, or both, in genetics, 2 of which have been in clinical cytogenetics; or (p)(2)(i) Hold an earned doctoral degree in a biological science, including biochemistry, or clinical laboratory science from an accredited institution; and (p)(2)(ii) Have 4 years of training or experience, or both, in genetics, 2 of which have been in clinical cytogenetics. (q) If the requirements of

	paragraph (b) of this section are not met and the laboratory performs tests in the specialty of immunohematology, the individual functioning as the technical supervisor must-- (q)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (q)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (q)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (q)(2)(ii) Have at least one year of laboratory training or experience, or both, in high complexity testing for the specialty of immunohematology. Note: The technical supervisor requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service. For example, an individual, who has a doctoral degree in chemistry and additionally has documentation of 1 year of laboratory experience working concurrently in high complexity testing in the specialties of microbiology and chemistry and 6 months of that work experience included high complexity testing in bacteriology, mycology, and mycobacteriology, would qualify as the technical supervisor for the specialty of chemistry and the subspecialties of bacteriology, mycology, and mycobacteriology. This STANDARD is not met as evidenced by: Based on review of Accreditation Organization COLA notification, laboratory staffing policy GEN-002, monthly instrument QC maintenance log review, supervisor license letter released by the Florida Department of Health (FDOH), and lack of documentation to support the minimum experience required for a Technical Supervisor and interview with Technical Supervisor (TS), the laboratory failed to have a qualified TS from 11/13/2020 to present. Findings included: - Review of CMS 209 Laboratory Personnel Report dated and signed by the Laboratory Director on 09 /08/2021 revealed the Technical Supervisor, General Supervisor and Testing Personnel was the same person. - Review of COLA Accreditation notification letter from date 11/13/2020 revealed the TS listed was the molecular technologist (MT). - Review of laboratory policy GEN-002 signed by the laboratory director on 11/24 /2020 showed the TS was MT. -Review of monthly instrument QC maintenance log from May to July of 2021, revealed that for the months of June and July, MT signed as TS. -Review of the delegation letter signed by the laboratory director (LD) on 03/10 /2021, revealed that the LD stated that he shared several duties with the Technical Supervisor (TS). -Review of the Supervisor license date for MT showed a date of 08 /11/2020. -Review of the MT resume revealed the experience listed for High Complexity Laboratory Technologist/Supervisor was Genome laboratory, since 04 /2018 - present. -Genome laboratory received the CLIA Registration Certificate on 09 /11/2020 -No documentation provided to support the minimum requirement of experience for the TS of testing in a High Complexity laboratory for a year. -During an interview on 09/09/2021 at 1:15 PM with TS (MT), he said that the laboratory director gave him a letter with delegation of duties as Supervisor on 03/10/2021. He also confirmed that he received the Supervisor license on 08/11/2021.
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 record review and interview, the laboratory failed to have a qualified General Supervisor. Refer to D6143.
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 review of CMS 209 Laboratory Personnel Report, supervisor license letter released by the Florida Department of Health (FDOH) to the General Supervisor (GS), lack of documentation to support the minimum experience required for a General Supervisor and interview with Technical Supervisor (TS), the laboratory failed to have a qualified GS from 11/13/2020 to present. Findings included: - Review of CMS 209 Laboratory Personnel Report dated and signed by the Laboratory Director on 09/08/2021 revealed that the Technical Supervisor, General Supervisor and Testing Personnel was the same person as the molecular technologist (MT). - Review of the Supervisor license date for MT showed a date of 08/11/2021. -No documentation to support the minimum requirement of experience for GS of 2 years of training or experience in a High Complexity laboratory. Refer to D 6111 -During an interview on 09/09/2021 at 1:20 PM with MT, he said that the laboratory director considered he was qualified to act as a GS from 11/20/2020. He also confirmed that he received the Supervisor license on 08/11/2021.
D6170	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(a) Each individual performing high complexity testing must possess a current license issued by the State in which the laboratory is located, if such licensing is required. This STANDARD is not met as evidenced by: Based on COLA laboratory records review, review of a temporary license letter released by the Florida Department of Health (FDOH), review of test records for the Roche Lightcycler 480 SARS-Cov-2 from 12/02/2020 to 12/10/2020 and interview with Technical Supervisor (TS), the Testing Personnel (TP) performed patient testing prior to receiving a Florida laboratory license. Findings include: -Review of COLA laboratory personnel records revealed that the laboratory had Laboratory Director A (LD-A) from 08/13/2020 to 11/13/2020 and (LD-B) acting from 11/20/2020 to present. - Review of CMS 209 Laboratory Personnel Report dated and signed by the Laboratory Director on 09/08/2021 revealed the Technical Supervisor, General Supervisor and Testing Personnel was the same person as the Molecular Technologist (MT). -Review of temporary license for MT as TP released by the FDOH revealed a date of 12/11/2020. -Review of Roche Lightcycler 480 SARS-Cov-2 records from 12 /02/2020 to 12/10/2020 revealed the tests were done by the MT, who did not have a temporary Florida license to perform testing during that time. During an interview on 09/08/2021 at 1:47 PM with MT, he said that the laboratory started testing on 09/11 /2020 and that while LD-A was acting as LD, the LD was the TP at that time, and he confirmed that after the change of LD, he (MT) was the TP for the days of reference.