Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D2168001	12/16/2020
Name of Provider or Supplier	**Street Address, City, State**	
Stat Laboratory Inc	10714 S Roberts Rd, Ste A, Palos Hills, 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
D3000	FACILITY ADMINISTRATION CFR(s): 493.1100 Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe. This CONDITION is not met as evidenced by: Based on review of the laboratory's application for CLIA Certification (116); testing menu; policies and procedures manuals; test results; and interview with the laboratory director (LD), the laboratory failed to report SARS CpV-2 test results to the Secretary during the Public Health Emergency as specified. Findings: 1. Review of the 116 revealed, under section "VIII. NON-WAIVED TESTING", the laboratory listed Sars-cov-2 IgG and IgM analytes tested using Beckman DXI 6000. 2. The laboratory listed Sars-cov-2 IgG and Sars- cov-2 IgM as analytes it tests. 3. Review of manufactures instructions for use revealed that the laboratory uses the ACCESS Immunoassay System (ACCESS SARS-CoV-2 IgG and ACCESS SARS- CoV-IgM) for use under the Emergency Use Authorization (EUA). The instructions state, "Laboratories within the United States and its territories are required to report all positive results to the appropriate public health authorities." Instructions also state, "Authorized laboratories using your product will have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate." 4. On December 15, 2020 at 2:30 PM, the surveyor requested a list of all Sars-cov -2 IgG and IgM test results from the date of initial testing (August 2020) through December 14, 2020.

	From the list the surveyor selected test results reported from November 4, 2020 through December 14, 2020; for a total of 145 test results reported. There was no documentation or record to show that test results were reported to public health authorities and/or the "Secretary", as required. 5. On December 15, 2020 at 3:00 PM, in an interview with the LD, the surveyor asked the LD how the lab reports its Sars-cov-2 results to public health. The LD stated that she did not know she was supposed to report Sars-cov- 2 tests results to Public Health. Thus, confirming the surveyor's findings.
D5300	PREANALYTIC SYSTEMS CFR(s): 493.1240 Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in 493.1241 and 493.1242, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the preanalytic systems and correct identified problems as specified in 493. 1249 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of laboratory policies and procedures manuals; patients' test requisitions; patients' test reports; and interview with the laboratory director (LD), the laboratory failed to monitor and evaluate the overall quality of the pre-analytic systems and correct identified problems as specified in 493.1249 for each specialty and subspecialty of testing performed. Findings: Review of the laboratory's procedures manual revealed, patients' tests are ordered from facilities using a written requisition form or electronic request. The following information must be entered on the requisition: A. Date B. Patient Name C. Date of Birth D. Sex E. Date and Time of Collection F. Test Order G. Ordering Physician Name 2. Review of patient's' test requisitions and corresponding patients' test reports revealed that tests were performed without proper authorization. See tag D5301 3. The surveyor could not determine that test requisition information was entered and / or transcribed into its LIS correctly. See tag D5309. 4. On December 16, 2020 at 11:30 AM, the LD confirmed the surveyor's findings.
D5301	TEST REQUEST CFR(s): 493.1241(a) The laboratory must have a written or electronic request for patient testing from an authorized person. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures manuals; patients' test requisitions; patients' test results; and interview with the laboratory director (LD), the laboratory failed to have a written or electronic request for patient testing from an authorized person. Findings: 1. Review of the laboratory's procedures manual revealed, patients' tests are ordered from facilities using a written requisition form or electronic request. The following information must be entered on the requisition: A. Date B. Patient Name C. Date of Birth D. Sex E. Date and Time of Collection F. Test Order G. Ordering Physician Name 2. On December 15, 2020 at 2:30 PM, the surveyor selected a total of 25 test requisitions along with their corresponding test

	results. There was no documentation to show who ordered tests for 2 of 25 test requisitions reviewed. The only information recorded on 2 0f 25 patients' test requisitions was patient name; date of birth; and test ordered. The words "weekly", every two weeks were written on 2 of 25 test requests reviewed. There were no written procedures for standing orders. 3. On December 15, 2020 at 2:45 PM, in an interview with the LD, they surveyor asked the LD why tests were analyzed and reported when the requisition was missing required information. The LD told the surveyor that because those patients were "walk-ins" requesting their own tests, the lab only enters the patient's name, Date of Birth, and the tests ordered. 4. On December 15, 2020 at 2: 45 PM, review of 25 patients test results revealed 2 of 25 patients test results were reported when there was no order from an authorized person. 5. On December 15, 2020 at 3:00 PM, the LD confirmed the surveyor's findings.
D5309	TEST REQUEST CFR(s): 493.1241(e) If the laboratory transcribes or enters test requisition or authorization information into a record system or a laboratory information system, the laboratory must ensure the information is transcribed or entered accurately. This STANDARD is not met as evidenced by: Based on review of test requisitions and interview with the laboratory director (LD), the laboratory failed to ensure the information is transcribed or entered accurately. Findings: 1. On December 16, 2020 at 11:00 AM, the surveyor selected 20 test requisitions for review. Review of the 20 requisitions revealed the following information: A. A date was hand written over the "DATE" and "DRAW ON." with permanent marker for 20 0f 20 requisitions reviewed. B. Due to the permanent marker covering information on the hard copy of the requisition, the surveyor could not determine if the "DATE" and DRAW ON" were entered into the LIS correctly when she compared the hard copy of the requisition to the LIS entry for 20 of 20 requisitions reviewed. 2. On December 16, 2020 at 11:30 AM, the LD confirmed the surveyor's 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 review of laboratory policies and procedures manuals; verification records; control procedure; and interview with the laboratory director, the laboratory failed to meet analytic systems requirements for each test; and monitor and evaluate the overall quality of the analytic systems for each specialty and subspecialty of testing it performs. Findings: 1. There is no documentation to show that the laboratory has a written procedure, that describes, specifically, the laboratory's pre-analytic, analytic, and post analytic activities from the test order through result reporting for each test it

	performs. See tag D5403 2. There is no documentation to show that laboratory could demonstrate the Accuracy, Precision, Reportable Range, and Normal Values for all its test systems for each specialty and /or subspecialty. See tag D5421 3. There is no documentation to show that the laboratory established the number, type, and frequency it performed testing on quality control materials. See tag D5441 4. On December 16, 2020 at 11:30 AM, the laboratory confirmed the surveyor's findings.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedures manual and interview with the laboratory director, the procedure manual failed to include the following: * Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. * Step-by-step performance of the procedure, including test calculations and interpretation of results. * Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. * Calibration and calibration verification procedures. * The reportable range for test results for the test system as established or verified in 493.1253. * Control procedures. * Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. * Limitations in the test methodology, including interfering substances. * Reference intervals (normal values). * Imminently life-threatening test results, or panic or alert values. * The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life-threatening results, or panic, or alert values. * Description of the course of action to take if a test system becomes inoperable. Findings: 1. Review of the laboratory's testing menu revealed that the laboratory performs the following tests: A. General Immunology, including Sars-CoV-2 IgG and IgM. B. Routine Chemistry C. Endocrinology D. Toxicology E. Hematology 2. Review of the laboratory's procedures manuals revealed that the laboratory used a generic generalized procedures manual that defined what should be in a procedures manual as defined by the regulations. The laboratory's procedures manual did not describe specifically the following for each test procedure listed

	above. A. Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. B. Step-by-step performance of the procedure, including test calculations and interpretation of results. C. Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. D. Calibration and calibration verification procedures. E. The reportable range for test results for the test system as established or verified in 493.1253. F. Control procedures. G. Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. H. Limitations in the test methodology, including interfering substances. I. Reference intervals (normal values). J. Imminently life-threatening test results, or panic or alert values. K. The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life-threatening results, or panic, or alert values. L. Description of the course of action to take if a test system becomes inoperable. 3. On December 15, 2020 at 11:00 AM, the laboratory director confirmed the surveyor's findings.
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 review of the laboratory's testing menu; test equipment; manufacturer's instructions; laboratory records; patients' test records; and interview with the laboratory director (LD), the laboratory failed to demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for each test system for the following parameters: *Accuracy *Precision *Reportable range of test results for the test system *Verification of reference intervals appropriate for the laboratory's population. Findings: 1. Review of the laboratory's testing menu revealed that the laboratory performed he following tests: A. General Immunology B. Routine Chemistry C. Toxicology D. Endocrinology E. Hematology 2. On December 15, 2020 at 9:30 AM, the surveyor was given a tour of the laboratory. Direct observation revealed, the laboratory performed testing using the following analyzers: A. Beckman DXC 700 AU - Routine Chemistry and Toxicology B. Beckman DXI 600 - Endocrinology and General Immunology C. Beckman DXH - Hematology (CBC) D. ALC ELITE -PT INR E. TOSHO G8- HGB A1C 3. On December 15, 2020 at 1:00 PM, review of documentation of verification performance revealed, there was no documentation to show that the laboratory verified the accuracy; reportable range; and reference intervals appropriate for the laboratory's population for the following tests: A. Beckman DXC 700 AU - Routine Chemistry and Toxicology B. Beckman DXI 600 - Endocrinology and General Immunology C. Beckman DXH - Hematology (CBC) D. ALC ELITE -PT INR E. TOSHO G8- HGB A1C 4. On December 15, 2020 at 1:30 PM, the surveyor asked the LD how it determined the reportable range of each tests. The LD told the surveyor that the lab just used the ranges that were recommended by the manufacturers of each test. There was no documentation to show

	that the laboratory ran specimens to show the accuracy and reportable range of each test method listed above. There was no documentation to show the LD reviewed data to determine verification of its test methods. 5. On December 15, 2020 at 1:30, the LD confirmed the surveyor's findings.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's testing menu; procedures manuals; and interview with the laboratory director (LD), the laboratory failed to establish the number, type and frequency of testing control materials using the performance specifications verified by the laboratory as specified in 493.1253(b)(3). Findings: 1. Review of the laboratory's testing menu revealed that the laboratory performed the following tests: A. General Immunology B. Routine Chemistry C. Endocrinology D. Toxicology E. Hematology 2. Review of laboratory procedures manuals revealed that there were not written procedures that described the number, type, and frequency it tests control materials for each test system or test. There were no procedures that describe, specifically, what to do when control materials do not give expected results for each test system. 3. On December 15, 2020 at 11:30 AM, the LD confirmed the surveyor's findings.
D5821	TEST REPORT CFR(s): 493.1291(k) When errors in the reported patient test results are detected, the laboratory must do the following: (k)(1) Promptly notify the authorized person ordering the test and, if applicable, the individual using the test results of reporting errors. (k)(2) Issue corrected reports promptly to the authorized person ordering the test and, if applicable, the individual using the test results. (k)(3) Maintain duplicates of the original report, as well as the corrected report. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions for reporting test results; patients' test reports; laboratory records; and interview with the laboratory director (LD), the laboratory failed do the following when errors in test results were detected in its SARs- CoV-2 IgG testing: * Promptly notify the authorized person ordering the test. * Issue corrected reports promptly to the authorized person ordering the test. Findings: 1. Review of manufacturer's information revealed instructions for interpreting and reporting SARs- CoV-2 IgG test results are as follows: A. Interpretation Non -

	Reactive - Report results as non-reactive for SARS-CoV-2 IgG antibodies B. Interpretation Equivocal - Report as equivocal C. Interpretation Reactive - Report result as reactive for SARS- CoV-2 IgG antibodies 2. On December 16, 2020 at 10:00 AM, Review of 10 SARs - CoV-2 IgG tests result from August 10, 2020 revealed, there was on documentation to show test results were reported for 10 of 10 patients' test reports reviewed. 3. On December 16, 2020 at 10:15 AM, in an interview with the LD, the LD stated that only a "-" was recorded for SARs-CoV-2 results on Auguste 10, 2020. 4. There was no documentation to show that a corrected report was issued when there was an error in reporting test results of SARs - CoV- 2 IgG results for 10 of 10 reports reviewed. 4. There was no documentation to show that the person requesting the test was notified of the error in reporting for 10 of 10 SARs - CoV- 2 IgG test reported. 5. On December 16, 2020 at 10:30 AM, the LD confirmed the surveyor's findings.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(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 postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on reveiw of the laboratory's policies and procedures manuals; review of patients test reports; and interview with the laboratory director (LD), the laboratory failed to establish and follow written policies and procedues for an ongoing mechanism to monitor, assess and, correct problems identified in the postanalytic sytems specified in 493.1291. Findings: 1. Review of the laboratory's policies and procedures manuals revealed, there were no procedures that described the laboratory's process for monitoring the laboratory's test result reporting process. 2. On December 16, 2020 at 10:00 AM, the surveyor reviewed 10 patients test reports from August 10, 2020 for Sars- CoV- 2 IgG test results. There was no documentation to show that Sars-CoV-2 IgG results was reported for 10 of 10 patients' test results reviewed. 3. On December 16, 2020 at 10:30 AM, in an intervew, the LD stated that the lab was aware of the error. 4. There was no documentation to show that the laboratory took corrective anctions when the reporting error occurred. See tag D5821. 5. On December 16, 2020 at 11:00 AM, the LD confirmed the surveyor's findings.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on review of verification procedures; test reports; personnel records; and interview with the laboratory director, the laboratory failed to have a director who provides overall management and direction of the laboratory. Findings: 1. Review of verification procedures revealed that the laboratory director failed to ensure that the laboratory perform and document all verification procedures for the Accuracy, Precision, and Reportable Range of its test methods. See tag D6013 2. Review of

	patients test reports revealed that the laboratory director failed to ensure that reports of test results include pertinent information required for interpretation. See tag D6026 3. Review of personnel records revealed that the laboratory director failed to ensure that all personnel had the proper education and experience prior to testing patients' specimens. See tag D6029
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) 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 review of manufactures procedures; verification records; and interview with the laboratory director (LD) the laboratory director failed to ensure verification procedure used are adequate to determine the accuracy, precision, and other performance characteristics of each test method it uses to perform testing. Findings: 1. Review of manufacturer's procedures for each test method revealed that there are instructions that instruct the laboratory how to perform verification of the Accuracy, Precision, and Reportable Range of each test method and specialty and subspecialty. The instructions included forms for the laboratory to document each step of the verification process for each test method and specialty and subspecialty. 2. Records show that the laboratory only documented "Simple Precision" procedures for each test method. There was no documentation to show that the laboratory demonstrated the Accuracy and Reportable Range for each test method for each specialty and subspecialty for the following: A. Beckman DXC 700 AU - Routine Chemistry and Toxicology B. Beckman DXI 600 - Endocrinology and General Immunology C. Beckman DXH - Hematology (CBC) D. ALC ELITE -PT INR E. TOSHO G8- HGB A1C See tag D5421 3. On December 15, 2020 at 1:00 PM, the LD confirmed the surveyor's findings.
D6026	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(8) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(8) Ensure that reports of test results include pertinent information required for interpretation. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions; test reports; and interview with the laboratory director (LD), the laboratory director failed to ensure that reports of test results include pertinent information required for interpretation of its Sars-CoV-2 IgG and Sars-CoV-2 IgM test results. Findings: 1. Review of manufacturer's instructions

	for performing Sars- CoV-2 IgG and Sars-CoV-2 IgM tests using the Access Immunoassay Systems revealed the following information as it pertained to testing: "The sensitivity of the Access SARS-CoV-2 assay after infection is unknown. Negative results do not preclude acute SARS-CoV-2 infection. If acute infection is suspected, direct testing for SARS-CoV-2 is necessary." 2. On December 15, 2020 at 3:00 PM the surveyor reviewed 145 SARS- CoV-2 test reports. A statement about the sensitivity of the Access SARS-CoV-2 test results was not included on reports of 145 of 145 test results reviewed. On August 10, 2020, the laboratory tested 10 patients specimens for CoV-2 IgG. There was no documenation to show that test results were reported for 10 of 10 patients' test reports reviewed. See tag D5821 3. On December 15, 2020 at 3:30 PM the LD confirmed the surveyor's findings.
D6028	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(10) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(10) Employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart; This STANDARD is not met as evidenced by: Based on direct observation; review of the laboratory's Clinical Laboratory Improvement Amendments Application for Certification (CMS - 116) and testing menu: Laboratory Personnel Report (CMS - 209); personnel records; and interview with the laboratory director (LD), the laboratory director failed to employ a sufficient number of laboratory personnel with the appropriate education and experience to accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart. Findings: 1. On December 15, 2020 at 9:30 AM, the surveyor was given a tour of the laboratory. The following analyzers were observed: A. Beckman DXC 700 AU - Routine Chemistry and Toxicology B. Beckman DXI 600 - Endocrinology and General Immunology C. Beckman DXH - Hematology (CBC) D. ALC ELITE - Hematology -PT INR E. TOSHO G8- HGB A1C 2. Review of the CMS -116 revealed that the laboratory recorded its total test volumes as 5,500. 3. Review of the CMS - 209 revealed that there was a total of 2 persons listed as moderate complexity testing personnel (TP). 4. Review of 2 TP's personnel records revealed that there was no documentation to show the qualifications of 1 of 2 TP. 5. On December 15, 2020, the LD confirmed the surveyor's findings.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can

	perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on review of Clinical Laboratory Improvement Amendments application for Certification of Compliance (Form 116); Laboratory Personnel Report (Form 209); personnel records; and interview with the laboratory director (LD); the LD failed to ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience to the type and complexity f the services offered. Findings: 1. Review of Form 116 reveals that the laboratory performs waived and moderate complexity testing. 2. Review of Form 209 reveals that the LD and 1 other person are listed as moderate complexity testing personnel. 3. Review of personnel records revealed that there was no documentation to show the qualifying educational credentials for 1 of 2 testing personnel. See tag D6065. 4. On December 15, 2020 at 10:00 AM, the LD confirmed the surveyor's findings.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on review of the laboratory's Clinical Laboratory Improvements Amendments Application for CLIA Certification of Compliance (Form 116); Laboratory Personnel Report (Form 209); personnel records and interview with the laboratory director (LD), the laboratory failed to have a sufficient number of individuals who meet the qualification requirements to perform the functions specified in 493.1425 for the volume and complexity of tests performed. Findings: 1. One of 2 testing personnel did not have the required credentials to show he qualifies to perform moderate complexity tests. See D60605 2. During survey date December 15, 2020 at 3:00 PM, the laboratory director told the surveyor she wants to hire more testing personnel but needed to get permission from the laboratory owner. Note: 1 of 2 testing personnel is the owner of the laboratory.
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy 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; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official 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); or (b)(4)(i) Have earned a high school diploma or equivalent; and

	This STANDARD is not met as evidenced by: Based on review of the Clinical Laboratory Improvement Application for Certification (CMS 116); Laboratory Personnel Report (CMS- 209); personnel records; and interview with the laboratory director (LD), testing personnel (TP) failed to meet educational requirements for performing moderate complexity testing. Findings: 1. Review of Form 116 revealed that the laboratory listed the following moderate complexity specialties and subspecialties on their application for CLIA Certification for a Certificate of Compliance: A. General Immunology B. Routine Chemistry C. Endocrinology D. Toxicology F. Hematology G. Waived Urinalysis H. Waived BNP 2. Review of Form 116 revealed that there was a total of 2 persons listed as testing persons (TP) for moderate complexity testing (the LD - TP # 1, as listed on the CMS -209 and one other person TP #2 as listed on CMS - 209). 3. Review of personnel records revealed the following information for the testing person not listed as LD: A. Testing personnel had foreign credentials. There was no documentation to show the US equivalent education was determined TP #2 as listed on the CMS 209. B. A document titled, "Evaluation of Laboratory Testing Personnel; Waived Tests," a check mark next to text, "High school, GED and documentation of training appropriate for the testing performed prior to analyzing patient specimens." C. Documentation to show TP #2was trained to perform both waived and moderate complexity testing in the laboratory. D. Documentation to show that the LD assigned TP # 2 as a "Generalist" in the laboratory. 4. On December 15, 2020 at 10:00 AM, they LD confirmed the surveyor's findings.