Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2097278	08/07/2019
Name of Provider or Supplier	**Street Address, City, State**	
Statlab Mobile	19101 Sw 108th Ave Unit 4, Miami, 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	An unannounced recertification survey, was conducted on 08/02/19 to 08/07/19 at Statlab Mobile. The laboratory was not in compliance with 42 CFR Part 493, Requirements for Clinical Laboratories. Based on the survey findings an Immediate Jeopardy situation was identified and the laboratory was notified at 3:30 PM 08/07/19. The laboratory failed to do quality control prior to patient testing (Beckman CoulterAcT 5diff CP) since at least 06/2017. Failed to validate new equipment prior to patient testing (Beckman Coulter AcT 5diff CP, Advia Centaur CP, Carolina CLC 720). Used expired reagents for patient testing on Beckman Coulter AcT 5diff CP, Carolina CLC 720. No room temperature or humidity were documented on days testing occurred. No records of calibrations for Beckman Coulter AcT 5 diff CP). No quality assurance (See D5400). The Laboratory Director failed to have oversight of the laboratory, failed to conduct competency evaluations on testing personnel, and failed to ensure testing personnel were qualified to perform testing prior to patient testing (See D6000). The following Conditions were not met: D5200- General Laboratory Systems 493.1230 D5300-Preanalytic Systems 493.1240 D5400-Analytic Systems 493.1250 D5800-Postanalytic Systems 493.1290 D6000-Moderate Complexity Laboratory Director 493.1403 D6063-Laboratory Testing Personnel 493.1421
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of American Proficiency Institute (API) and Medical Laboratory Evaluation (MLE) proficiency testing records and interview with Owner, the facility failed to have documentation of signed attestation by the laboratory director or

	designee for 6 out of 6 events reviewed for Chemistry and Hematology. Findings Included: Review of MLE proficiency records (enrolled in this program till 2017) revealed that the laboratory failed to have documentation of the attestation signed by the Laboratory Director and the Testing Person for the 2nd and 3rd event of 2017 for the specialties of Chemistry and Hematology. Review of API (enrolled in this program since 2018 1st event) proficiency records revealed that the laboratory failed to have documentation of the attestation signed by the Laboratory Director and the Testing Person for 1st, 2nd and 3rd event of 2018, and 1st event 2019 for the specialties of Chemistry and Hematology. During an interview on 08/02/19 at 2:30 PM, the owner confirmed that the laboratory failed to sign the attestations of reference.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on lack of proficiency testing records and interview with laboratory owner, the facility failed to have documentation of preparation, processing, examination and each step in the testing and reporting of results for all proficiency testing samples for 6 out of 6 events reviewed for Chemistry and Hematology. Findings Included: Review of American Proficiency Institute and Medical Laboratory Evaluation proficiency records revealed that the laboratory failed to have documentation of preparation, processing, examination and each step in the testing and reporting of results for all proficiency testing samples for the 2nd and 3rd events of 2017; 1st, 2nd and 3rd events of 2018 and 1st event of 2019 for the specialties of Chemistry and Hematology. During an interview on 08/02/19 at 2:30 PM, the Owner confirmed that the laboratory failed to have the required documentation of the proficiency testing.
D2123	HEMATOLOGY CFR(s): 493.851(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events.

	This STANDARD is not met as evidenced by: Based on review of the American Proficiency Institute (API) documentation and interview with the Owner, the laboratory failed to participate in proficiency testing (PT) program, which resulted in a score of zero (0) percent on the Hematology /Coagulation 1st event in 2019. Findings Included: Review of the API records for the 2019 Hematology/Coagulation, 1st event showed the laboratory received a score of 0% for all analytes to be tested. The notes on the API "Performance Summary" sheet stated "Failure to Participate". During an interview on 08/02/19 at 2:30 PM, the Owner acknowledged that the laboratory failed to get tests results submitted on time and confirmed that patient testing was being performed during this timeframe.
D5200	GENERAL LABORATORY SYSTEMS CFR(s): 493.1230 Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, 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 general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of the American Proficiency Institute (API) documentation and interview with the Owner, the laboratory failed to participate in proficiency testing (PT) program, which resulted in a score of zero (0) percent on the Hematology /Coagulation 1st event in 2019. Findings Included: Review of the API records for the 2019 Hematology/Coagulation, 1st event showed the laboratory received a score of 0% for all analytes to be tested. The notes on the API "Performance Summary" sheet stated "Failure to Participate". During an interview on 08/02/19 at 2:30 PM, the Owner acknowledged that the laboratory failed to get tests results submitted on time and confirmed that patient testing was being performed during this timeframe.
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 the lack of documentation and interview with Laboratory Owner, the laboratory failed to document the annual competency assessment on 1 out of 1 testing personnel (TP); for a period of 3 out of 3 years (2017-2019) reviewed. Findings Included: The laboratory failed to have documentation of annual competency assessment on 2017, 2018, 2019 for TP. During an interview on 08/02/19 at 4:30 PM with the owner, he confirmed that there was no competency assessment documented for the period of above reference for the TP.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on record review and interview with the Laboratory Owner, the laboratory failed to have a General Laboratory Systems Quality Assurance Policy for at least the period of 2 out of 2 years (2017-2019) reviewed. This is a repeated deficiency found during the 06/08/17 recertification survey. Findings Included: Review of the procedure manual revealed that there was no Quality Assurance Policy or program established to monitor and evaluate the ongoing and overall quality of total testing processes, to evaluate the quality of tests results, and to identify perform corrections of its problems as needed in the general laboratory systems. During an interview on 08 /05/19 at 3:24 PM, the Owner acknowledged that there was no quality assurance in the procedure manual and no documentation of the quality assurance activity. The recertification survey dated 06/08/19 stated in the Plan of Correction that the "QA Policy was in place at time of survey. Supporting documentation provided." However, no documentation was provided while on survey.
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 record review and interview with the Laboratory Owner, the laboratory failed to have a Pre-analytic Quality Assurance Policy for at least 2 out of 2 years (2017-2019) reviewed (See D5391).
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(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 preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on record review and interview with the Laboratory Owner, the laboratory failed to have a Pre-analytic Quality Assurance Policy for at least 2 out of 2 years (2017-2019) reviewed. This is a repeated deficiency from the 06/08/17 recertification survey. Findings Included: Review of the procedure manual revealed that there was no Quality Assurance Policy, to monitor and evaluate the ongoing and overall quality of total testing process, to evaluate its policies and procedures, and to identify and

	maintain correction of its problems for the pre-analytic systems. During an interview on 08/05/19 at 3:24 PM, the Owner acknowledged that there was no quality assurance in the procedure manual and no documentation of the quality assurance activity. The recertification survey dated 06/08/17 stated in the Plan of Correction that the "All items listed are within the procedure manual. Supporting documents attached.." No documentation was provided while on survey.
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: 39027 Based on observation, record review, and interview with Owner, the laboratory failed to have documentation showing that the Laboratory Director review and sign the procedure manual as per quality management program (See D5407), failed to monitor room temperature and humidity (See D5413), used expired reagents (See D5417), failed to perform equipment validation (See D5421), failed to perform daily maintenance and function checks (See D5429), failed to perform calibration on Beckman Coulter AC-T 5 Diff (See D5439), failed to run controls prior to patient testing (See D5447) and failed to have at least 2 acceptable controls prior patient testing (See D5481).
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on record review and interview with Owner, the Laboratory Director failed to review and sign the procedure manual updates since June of 2017. Findings Included: Review of the laboratory's procedure manual in the Quality Management Program, revealed that the Laboratory Director will sign and date the procedure manual at least biannually. Review of equipment in use, revealed that new equipment was added after last survey on 6/8/2017. The new equipment included Beckman Coulter Ac-T 5diff added on November 2017, Siemens Advia Centaur CP added on June 2018 and Caroline CLC 720 added on February 2019. However, the Laboratory Director failed to update the procedure manual to include the new equipment. No documentation of the laboratory director signature and review found at the time of the survey. During an interview on 08/05/19 at 3:24 PM, the Owner acknowledged that the procedure manual was not reviewed, signed and dated by the Laboratory Director since 2017.
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 user manual review and interview with Laboratory Owner, the laboratory failed to monitor and document room temperature and humidity, which are requirements to assure optimal operation of the analyzers during the period of 2 out 2 years (2017-2019) reviewed. Findings Included: Review of environmental logs from 11/2017 to 07/2019, revealed that there was no record of room temperature and humidity for the years of 2017, 2018 and 2019. Review of Sysmex CA 500 coagulation analyzer revealed a room temperature range requirement of 15- 35 C and humidity of 30-85 %. No records were found for these requirements. Review of the Hematology analyzer Beckman Coulter AC-T 5 diff user manual revealed a room temperature requirement range of 16 to 34 C. No documentation of the room temperature logs were found for 2017, 2018 and 2019. Review of Advia Centaur CP manual revealed a room temperature range requirement of 18-30 C and room humidity of 20-85 %. No documentation of the temperatures for this requirement was found. Review of the Carolina CLC 720 analyzer user manual indicates that the operation temperature range is 15 to 30 C and humidity between 35 to 85 %. There was no documentation of the temperature and humidity of the laboratory room. During an interview on 08/02/18 at 4:30 PM, the Owner confirmed that there was no record of room and humidity documented.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on observation and interview with Owner, the laboratory had expired reagents in use since at least 2017. Findings include: Observation of the Analyzer Coulter AcT 5, the laboratory had the following reagents expired in use: multi diluent (2) expired on 6/27/19, CBC rinse expired on 7/19/18, Basolyse II expired on 12/7/17, Lysebio expired on 5/17/19 , CBC diluent expired on 1/23/19. Observation of the Carolina liquid chemistry CLC 720 chemistry analyzer had the following expired reagents in use: Carolina fast detergent (2) both expired on 3/31/19, fast detergent (1) expired on 5 /31/19. Also, on the Carolina instrument; ALT R2 (Alanine transferase) expired on 2 /28/19, Tbili R2 (Total bilirubin) expired on 7/31/19; Tbili R1 expired on 7/31/19, Alp R2 expired on 6/30/19, Calcium expired on 5/31/19, Albumin exp 3/31/19, CO2 (Carbon dioxide) expired on 4/30/19. Observations of the Advia Centaur CP reagents revealed TSH (Thyroid Stimulating Hormone) expired on 7/13/19. During an interview on 08/02/19 at 4:30 PM the Owner confirmed the laboratory had the expired reagents in use for patient testing.

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 record review and interview with the Laboratory Owner, the laboratory failed to do the performance verification of the lab Beckman Coulter AcT 5 Diff CP in use since November 2017. Advia CP Centaur in use since June 2018, and the Carolina CLC 720 in use since January 2019 before starting patient testing. The laboratory failed to provide documentation to show that validation of equipment performance was completed prior to patient testing. This is a repeated deficiency from the initial certification survey conducted on 07/30/15; in which it was noted that new equipment was added to the laboratory without validation of performance completed prior to patient testing. Findings Included: Review of Medical Laboratory Evaluation (MLE) proficiency testing (PT) records revealed that the Beckman Coulter AC-T 5 diff was in use to test PT samples in the last term of 2017. No validation records were available for this equipment prior to starting patient testing. Review of MLE PT records and maintenance records revealed that the Advia Centaur was in use since June of 2018. No documentation was found to show a validation study performed on this equipment before starting patient testing. Review of American Proficiency Institute (API) PT records for 2019, revealed that the use of the Carolina CLC 720 during the remediation plan in April 2019 was conducted without prior validation of performance prior to patient testing since January 2019. No documentation of the validation prior to patient testing was found. During an interview on 08/05/19 at 4:30 PM, the owner acknowledged that no validations were performed on the equipment of reference before patients testing started.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on lack of records and interview with the Owner, the laboratory failed to document the daily start up and shutdown to Hematology Analyzer Coulter AcT 5 diff for the period of 2 out of 2 years (2017-2019) reviewed. Findings Included: Review of user manual for the Analyzer Coulter AcT 5, requires a daily start up showing that all parameters passed and a daily shutdown. There were no records of daily start up and shut down for Hematology Analyzer Coulter AcT diff found since November 2017. During an interview on 08/02/19 at 4:30 PM the Owner confirmed the laboratory failed to have documentation of the daily maintenance for the period reviewed.

D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on record review and interview with the Laboratory Owner, the laboratory failed to keep and provide documentation showing that the Beckman Coulter AcT 5 diff, Sysmex CA 500, Advia CP Centaur, and Carolina CLC 720 analyzer's calibration verification was performed at least every 6 months as required, during the period of 2 out of 2 years reviewed (2017-2019). Findings Included: Review of Laboratory records showed no documentation of calibration verification was available to show evidence of calibrations or calibration verification being performed on the above equipment since 2017. During an interview on 08/02/19 at 5:00 PM, the Owner confirmed that the facility failed to perform calibration verifications.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on lack of documentation and interview with the Owner, the laboratory failed to run controls on Hematology Analyzer Coulter AcT 5 diff for Complete Blood Counts (CBC) with Differential, prior to performing patient testing for a period of 2 out of 2 years (2017-2019) reviewed. Findings Included: Based on lack of documentation of the Analyzer Coulter AcT 5 runs, the laboratory failed to test quality controls samples before performing patient testing since at least June 2017. On March 2019, the laboratory reported 44 CBC with Differential tests. The CBC with

	Differential study include the following tests: White Blood Cells (WBC) count, Red Blood Cells (RBC) count, Hemoglobin, Hematocrit, Mean Corpuscular Volume (MCV), Mean Corpuscular Hemoglobin(MCH), Mean Corpuscular Hemoglobin Concentration (MCHC), Red Cell Distribution Width (RDW), Platelet Count, Mean Platelet Volume (MPV), Neutrophils %, Monocytes %, Eosinophils, BAS %, Neutrophils #, Lymphocytes #, Monocytes #, Eosinophils#, BAS #. During an interview on 08/02/2019 at 4:30 PM, the Owner confirmed that he was the person responsible for purchasing, reagents and controls and he did not remember the last time he purchased CBC controls nor could he find that any controls were ran since at least June 2017.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on Carolina CLC 720 quality control (QC) record review and interview with the Owner, the laboratory failed to have 2 level controls within acceptable range for Creatinine prior to patient testing for 37 out 99 testing dates reviewed; and the laboratory failed to follow manufacturer's instructions for QC ranges. Findings Included: 1-Review of Chemistry Controls Level I and Level II control, lot #724001 for low control (I) and Lot 717402 for high control (II) for Creatinine level revealed the following expected range: -Level I: mean 1,04 0.30 for an expected range of 0.44-1.64, the Levy Jennings log had a range 0.2-1.88. -Level II: mean 5.36 0.8 for an expected range of 3.76-6.96, the Levy Jennings log had a range of 3.04-7.56. 2-Review of QC records for Carolina CLC 720 revealed that for testing dates since February 1, 2019, at least one out of two controls were out during the following dates: February:1, 4, 5, 6, 12, 13, 14, 18, 22, 28 March: 3, 20, 21, 22, 25, 26, 27, 28 May: 2, 10, 13, 14, 16, 17, 20, 21, 22, 23, 24, 27, 28, 29 July:2, 3, 8, 12, 23 During an interview on 08/07/19 at 5:30 PM with the Owner, it was confirmed that the range in the Levy Jennings log did not have the correct range and that on the days of above-referenced the controls were out. Review of the manufacturer's expected values for level 1 controls revealed that the laboratory was using incorrect ranges for every analyte ran (including Albumin, Alkaline Phosphatase, Alanine transferase, Aspartate aminotrasferase, Total bilirubin, Blood urea nitrogen, Calcium, Cholesterol, Carbon dioxide, Creatinine, Glucose, HDL cholesterol, Hemoglobin A1C, LDL cholesterol, Total protein, Triglycerides, and Vitamin D). Interview on 08/07/19 at 5:30 PM with the Owner confirmed that the ranges entered into the Laboratory Computer System (LIS) for controls were not the ranges that the manufacturer required.
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 with the Laboratory Owner, the laboratory failed to have a Analytic Quality Assurance Policy for at least 2 out of 2 years (2017-2019) reviewed. This is a repeated deficiency from the 06/08/17 recertification survey. Findings Included: Review of the procedure manual revealed that there was no Quality Assurance Policy, to monitor and evaluate the ongoing and overall quality of total testing process, to evaluate its policies and procedures, and to identify and maintain correction of its problems for the -analytic systems. During an interview on 08/05/19 at 3:24 PM, the Owner acknowledged that there was no quality assurance in the procedure manual and no documentation of the quality assurance activity. The recertification survey dated 06/08/19 stated in the Plan of Correction that the "All items listed are within the procedure manual. Supporting documents attached.." No documentation was provided while on survey.
D5800	POSTANALYTIC SYSTEMS CFR(s): 493.1290 Each laboratory that performs nonwaived testing must meet the applicable postanalytic systems requirements in 493.1291 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 postanalytic systems and correct identified problems as specified in 493. 1299 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on record review and interview with the Laboratory Owner, the laboratory failed to have a Post-analytic Quality Assurance Policy for at least 2 out of 2 years (2017-2019) reviewed (See D5891).
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on record review and interview with the Owner, the laboratory failed to have the location of where the testing was performed for 7 out of 7 months (January-July 2019) reviewed. Findings Included: Patient reports were pulled from January 2019 (56 patient reports), February 2019 (32 patient reports), March 2019 (38 patient reports), April 2019 (36 patient reports), May 2019 (6 patients), June 2019 (3 patients), and July 2019 (14 patient reports). The address of where patient testing was performed was not on any of the 185 patient reports. During an interview on 08/07/19 at 2:00 PM; the Owner confirmed that the address of where the patient testing was performed was not on the final patient reports.

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 record review and interview with the Laboratory Owner, the laboratory failed to have a Post-analytic Quality Assurance Policy for at least 2 out of 2 years (2017-2019) reviewed. This is a repeated deficiency from the 06/08/17 recertification survey. Findings Included: Review of the procedure manual revealed that there was no Quality Assurance Policy, to monitor and evaluate the ongoing and overall quality of total testing process, to evaluate its policies and procedures, and to identify and maintain correction of its problems for the post-analytic systems. During an interview on 08/05/19 at 3:24 PM, the Owner acknowledged that there was no quality assurance in the procedure manual and no documentation of the quality assurance activity. The recertification survey dated 06/08/17 stated in the Plan of Correction that the "The pos-analytic systems currently in place is monitored by the MT. The MT evaluates all required controls, calibrations, and system errors for each analyzer. A log of results as well as error corrections are documented and then presented to Med Director during bi-weekly visit.." No documentation was provided while on survey.
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: 39027 Based on record review and staff interview, the laboratory director failed to provide sufficient oversight of the laboratory's specimen testing process for a period of 2 out of 2 years (2017-2019). Findings Included: 1. The Laboratory Director failed to oversee the laboratory operations. Refer to D6004. 2. The Laboratory Director failed to have oversight of the proficiency testing activity of the laboratory. Refer to D6015. 3. The Laboratory Director failed to ensure the laboratory took corrective action when quality controls (QC) results were not run per procedure. Refer to D6020. 4. The Laboratory Director failed to ensure the laboratory had a Quality Assessment system in place. Refer to D6021. 5. The Laboratory Director failed to ensure the laboratory had a process in place to evaluate personnel competency of the staff performing moderate complexity testing. Refer to D6030. .
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b) 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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical

	consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on observation, record review and interview with Laboratory Director, the Laboratory Director failed to effectively oversee the laboratory for a period of 2 out of 2 years (2017-2019) reviewed. Findings Included: See D5200, D5300, D5400, D5800 for the laboratory director failure to oversee the laboratory. Interview via telephone on 08/06/19 at 1:04 PM; the Laboratory Director confirmed that he has not been there since 2017.
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) 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)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory director failed to provide overall management and direction to ensure the laboratory's proficiency activity for a period of 2 of 2 years (2017-2019) reviewed. Findings Included: See D2009 for failure to ensure attestation signed and results reviewed. See D2015 for failure to ensure the laboratory kept all records of proficiency testing. See D2123 for failure to submit results for Hematology specialty 1st event of 2019.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on observation, record review and interview with Laboratory Owner, the Laboratory Director failed to effectively oversee the laboratory and to ensure a Quality Control program that was effective for a period of 2 out of 2 years (2017-2019) reviewed. Findings Included: See D5447 for failure to run CBC controls prior to patient testing. See D5481 for failure to ensure at least 2 controls were acceptable before patient testing using the Carolina CLC 720 analyzer.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES

	CFR(s): 493.1407(e)(5) 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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on record review and staff interview, the Laboratory Director failed to establish and follow a quality assurance program (QA) for the period of 2 out of 2 years (2017-2019) reviewed. Findings Included: See D5291, D5391, D5491, and D5891 for failure to ensure there was a QA program in place.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) 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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory director failed to ensure a personnel competency program was in place to evaluate staff competency for the period of 2 out of 2 years (2017-2019) reviewed. Findings Included: See D5209 for failure to perform annual competency evaluations. See D6063 for failure to ensure testing staff are licensed and their education verified prior to patient testing.
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 record review and interview with the owner, the laboratory failed to ensure that a licensed Staff performed patient testing (See D6064), and also failed to verify the education of the Testing Person (See D6065).
D6064	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(a)

	Each individual performing moderte 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 observation and interview with the Laboratory Owner, he confirmed that he performed testing without having a valid license. This is a repeated deficiency from the initial certification survey conducted on 07/30/15. Findings Included: During the survey the Owner was observed with the instruments and computer system. During an interview on 08/07/19 at 11:30 AM, the Owner confirmed that he has performed patient testing. He could not recall how many patients he tested or what days he tested. The Owner confirmed that he did not have a valid State of Florida Clinical Laboratory Personnel license. The plan of correction (signed by the Laboratory Director on 08/10/15) from the initial certification survey conducted on 07/30/15 stated "To ensure personnel qualification are met in the future, no technologist, or technician will be granted employment without first furnishing his/her national accreditation and current State of Florida clinical laboratory personnel license." It also stated that "For all and any test going forward, the medical director will monitor they complete process."
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 record review and interview with the Owner, the laboratory failed to verify the education of 1 out 1, Testing Person listed on the CMS 209. There was also, 1 out of 1 unlicensed Testing staff with no verification of education. Findings Included: Review of CMS 209, Laboratory Personnel Report, signed by the Laboratory Director on 08/02/19, revealed testing person # 1 held position of Testing person (TP) for moderate complexity. Review of personnel files revealed no documentation of education for TP 1. There was no documentation of education for the unlicensed Testing Person. During an interview on 08/02/19 at 11:30 AM, the Owner confirmed that the laboratory only had the license but no proof of education for TP 1 and that he did not have copy of his education (the unlicensed Testing Person).