Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D2143005	12/11/2019
Name of Provider or Supplier	**Street Address, City, State**	
Life Enhancement Medical Services, Pllc	2716 Troxler Road, Burlington, NC	

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
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, the absence of records, and interview with the laboratory director 12/11/19, the laboratory failed to enroll in proficiency testing or establish a system for verifying the accuracy of its urine toxicology testing at least twice a year. The laboratory's "QUALITY MANUAL" states "... 5.6 Assuring the quality of test results ... The laboratory is enrolled in proficiency testing program in compliance with CLIA and/or COLA requirements or otherwise perform split sample analysis with another accredited laboratory for all analytes offered on the test menu. ..." There were no proficiency testing records available for review during the survey. During interview at approximately 9:45 a.m., the laboratory director confirmed that the laboratory was not enrolled in proficiency testing and he verified that the laboratory did not have a system in place to verify the accuracy of its urine toxicology testing at least twice a year.
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 review of the laboratory's procedure manual and interview with TP (testing personnel) 12/11/19, the laboratory's procedure manual had not been approved by the

	current laboratory director. Review of the laboratory's procedure manual revealed the procedures had not been signed and dated by the laboratory's current laboratory director to indicate review and approval. During interview at approximately 12:45 p. m., TP #1 verified that the procedures in the manual were the ones in use. She confirmed they had not been signed and dated by the laboratory director.
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 review of the laboratory's policies and procedures, the absence of records, and interview with TP (testing personnel) 12/11/19, the laboratory failed to monitor and document room temperature and humidity in the room used for operation of the Agilent 6460 analyzer. The laboratory's "Environmental Conditions - Control & Monitoring" procedure states "... 5. Procedures: ... 5.2 Daily verify that the temperature and relative humidity of the lab are within the acceptable range (temperature 15-35 degrees C) or humidity (40-80%). Record the check on the Temperature and Humidity Log. ..." The laboratory's "QUALITY MANUAL" states "... 5. ... 5.2 Accommodation and Environmental Conditions The laboratory's environmental conditions are monitored and controlled by the laboratory staff. The laboratory controls temperature levels in the testing environment and provides appropriate storage and handling of test samples/specimens as required. Testing is suspended when environmental conditions are outside of the acceptable limits ..." There were no temperature and humidity records available for review at the time of the survey for the room where the Agilent 6460 analyzer is operated. During interview at approximately 3:25 p.m., TP #1 verified there were no temperature and humidity records available for this area. She stated that they do not monitor the temperature and humidity in the room where the Agilent 6460 analyzer is operated. She stated the room does not have a thermometer or humidity gauge.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on observation 12/11/19, the laboratory failed to label solutions with all required information. Findings: 1. During a tour of the laboratory at approximately 2: 15 p.m., the surveyor observed the following items in the flammables cabinet in the

	room where the Agilent 6460 analyzer is operated: a. 1 bottle with a handwritten label "Methanol". The label did not include storage requirements or expiration date. b. 1 bottle of unidentified clear liquid with a faded label. The information on the label was unclear. 2. During a tour of the laboratory at approximately 4:10 p.m., the surveyor observed a small amber vial without a label to indicate identity, storage requirements, or preparation/expiration dates in the specimen processing area freezer.
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 the laboratory director 12/11/19, the laboratory failed to discard supplies that had exceeded their expiration dates. Findings: 1. During a tour of the laboratory at approximately 2:15 p.m., the surveyor observed the following expired supplies in the laboratory's freezer, available for use: a. 1 vial labeled "BG QC" with lot #18335BG and expiration date 3/19; b. 1 vial labeled "Neg" with lot #19015Cal and expiration date 4/19; c. 1 vial labeled "1/2 Cal" with lot #19015Cal and expiration date 4/19; d. 1 vial labeled "Blank" with lot #19015Cal and expiration date 4/19; e. 1 vial labeled "Low QC" with lot #19015QC and expiration date 4/19; f. 6 vials labeled "Cal 1", "Cal 2", "Cal 3", "Cal 4", "Cal 5", and "Cal 6" with lot #19085QC and expiration date 5/19; g. 1 vial labeled "BG QC" with lot #19041BG and expiration date 5/19; h. 1 vial labeled "Low QC" with lot #19085QC and expiration date 5/19; i. 1 vial labeled "Cal 7" with lot #19085Cal and expiration date 5/19; j. 1 vial labeled "High QC" with lot #19085QC and expiration date 5/19. 2. During a tour of the laborarory at aproximately 4:10 p.m., the surveyor obseved the following expired items in the refrigerator across from the CLC 800 analyzer, available for use: a. MGC Primary DAU Control Set with lot # 72994619 and expiration date 11/30/2019; b. DRI Multi-Drug Urine Calibrator 2 with lot #73272681 and expiration date 9/30/2019. 3. During a tour of the laboratory at approximately 4:10 p.m., the surveyor observed the following expired supplies in the laboratory, available for use: a. Fast Detergent Alkaline Wash Sloution with lot #M1808 and expiration date 9/30/19 on a shelf under the computer; b. 1 bottle of Cerilliant standard with lot #FN11021501 and expiration date 11/2019 in the freezer in the laboratory's specimen processing area. During interview at approximately 4:25 p.m., the laboratory director stated some of the expired supplies might have been used during instrument validation, but had not been used since then.
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 review of five random test reports (accession # UR19-21069, UR19-21210, UR19-12558, UR19-8300, UR19-10001) and interview with the laboratory director 12 /11/19, the laboratory's test reports did not include all required information. Review of five random patient test reports (accession # UR19-21069, UR19-21210, UR19-12558, UR19-8300, UR19-10001) revealed the test reports included the name and CLIA number of the laboratory's sister laboratory which operates in the same space as the laboratory on alternate days, but did not include the laboratory's name. During interview at approximately 4:20 p.m., the laboratory director stated he did not realize test reports had the sister laboratory's name and CLIA number on them.
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 review of 2019 laboratory records, the laboratory director failed to provide overall management and direction for the laboratory. Findings: 1. The laboratory director failed to ensure verification procedures were adequate to determine pertinent performance characteristics for urine toxicology testing performed by the laboratory (see D8086). 2. The laboratory director failed to ensure the establishment and maintenance of an effective quality assessment program (see D6094). 3. The laboratory director failed to ensure the establishment and maintenance of acceptable levels of analytical performance for urine toxicology testing (D6095). 4. The laboratory director failed to ensure all testing personnel were trained prior to testing patient specimens (see D6102). 5. The laboratory director failed to ensure the establishment of policies and procedures for evaluating the competency of testing personnel (see D6103). 6. The laboratory director failed to ensure that an approved procedure manual was available for all aspects of the testing and reporting process (see D6106). 7. The laboratory director failed to ensure a list of authorized duties and responsibilities was available for all testing personnel (see D6107).
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 review of validation records, the absence of records, and interview with TP (testing personnel) 12/11/19, the laboratory director failed to ensure verification procedures were adequate to determine pertinent performance characteristics for urine toxicology testing performed by the laboratory. 1. The laboratory failed to enroll in proficiency testing or establish a system for verifying the accuracy of its urine toxicology testing at least twice a year (see D5217). 2. The laboratory's validation

	failed to include a frozen specimen stability study for the laboratory's current analyzer, the CLC 800. During interview at approximately 4:00 p.m., TP #1 stated that the laboratory freezes specimens if there is insufficient information on the requisition or if there is a problem with testing. She stated the laboratory did perform a stability study as part of their validation, but the specimens from the stability study were tested on the ImmTox analyzer.
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 review of the laboratory's quality assessment plan and review of 2019 laboratory records 12/11/19, the laboratory director failed to ensure the maintenance of an effective quality assessment program designed to identify and correct problems and prevent their recurrence. Findings: The laboratory's 'QUALITY ASSESSMENT PLAN" states "... Goals: ... Improve the overall quality and efficiency of the laboratory service. Evaluate the effectiveness of the laboratory's policies and procedures Identify problems and make corrections to prevent recurrences Prevent recurring problems Assure accurate, reliable and prompt performance of tests and reporting results ..." The plan included a calendar indicating review of a monthly checklist with additional areas such as patient test management, proficiency testing, personnel, and procedures to be monitored in 8 of 12 months. Review of 2019 laboratory records revealed the laboratory's quality assessment program had not been used effectively to identify problems identified during the survey in the following areas: a. proficiency testing / accuracy verification (see D5217, D6086); b. procedure manual (see D5407, D6106); c. test systems, equipment, reagents (see D5413, D5415, D5417, D6095); d. test reports (see D5805); e. personnel (see D6102, D6103, D6107).
D6095	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(6) The laboratory director must ensure the establishment and maintenance of acceptable levels of analytical performance for each test system. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, the absence of records, and interview with TP (testing personnel) 12/11/19, the laboratory director failed to ensure the establishment and maintenance of acceptable levels of analytical performance for the Agilent 6460 analyzer. The laboratory failed to monitor and document room temperature and humidity in the room used for operation of the Agilent 6460 analyzer (see D5413).
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must 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 personnel records and interview with the laboratory director 12/11/19, the laboratory director failed to ensure that all personnel received appropriate training and could perform all testing operations reliably prior to reporting patient test results. Review of personnel records revealed there was no training documentation available for TP #2. During interview at approximately 11:45 a.m., the laboratory director stated that TP #2 sometimes performs interpretations for confirmation testing performed on the Agilent 6460 or the Sciex API 4000 LCMS (liquid chromatography mass spectrometry) analyzers. He stated TP #2 trained TP #1, and he confirmed there were no training records available for TP #2.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must 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 review of the laboratory's policies and procedures and review of personnel records 12/11/19, the laboratory director failed to ensure the establishment of policies and procedures for evaluating the competency of TP (testing personnel) for all phases of the testing and reporting process. The laboratory's "Quality Manual" states "... 5. Technical Requirements 5.1 Personnel ... Competency is evaluated during on-the-job training, proficiency testing and randomly during the technical audits of test methods. ..." The laboratory did not have a detailed competency evaluation procedure which described the process for evaluation, the frequency, who is responsible, and the steps to take if competency requirements are not met. Review of personnel records revealed TP #1 had a competency evaluation dated 11/19/18 (before the laboratory started patient testing) which was performed for another laboratory and did not indicate specific instruments/tests that were included in the evaluation. There were no competency evaluation records available for TP #2.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. This STANDARD is not met as evidenced by: Review of the laboratory's policies and procedures and interview with the laboratory director and TP (testing personnel) 12/11/19, the laboratory director failed to ensure that an approved procedure manual was available for all aspects of the testing and

	reporting process. Findings: 1. Review of the laboratory's policies and procedures revealed the laboratory had three different paper procedure manuals: one labeled with the name of a sister laboratory, one labeled with the name of a management company, and one with no label. It was unclear which manual contained the procedures utilized by the laboratory. During interview at approximately 12:45 p.m., TP #1 stated that the unlabeled manual contained the laboratory's current procedures. During interview at approximately 4:30 p.m., the laboratory director showed surveyors an online procedure manual provided by a management company. The procedures were generic and were not specific for the laboratory. The laboratory director stated he could customize the procedures. 2. The laboratory's policies and procedures had not been signed and dated by the laboratory director to indicate review and approval (see D5407).
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of personnel records and interview with the laboratory director 12/17 /19, the laboratory director failed to specify, in writing, the duties and responsibilities for 2 of 2 TP (testing personnel) for all phases of the testing and reporting process. Findings: 1. Review of personnel records for TP #1 revealed a generic "Testing Personnel Job Description". The job description was not specific and did not include a list of tests TP #1 was authorized to perform or analyzers TP #1 was authorized to operate. 2. Review of personnel records revealed there was no job description or list of duties and responsibilities available for TP #2. During interview at approximately 11:45 a.m., the laboratory director stated that TP #1 performs urine drug screens on the CLC 800 analyzers and prepares and runs specimens on the Agilent 6460 and Sciex API 4000. He stated that TP #2 sometimes performs interpretations for confirmation testing performed on the Agilent 6460 or the Sciex API 4000.