Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D0677093	05/06/2021
Name of Provider or Supplier	**Street Address, City, State**	
Cliffside Medical Emergimed Laboratory	663 Palisade Ave, Cliffside Park, NJ	

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
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 surveyor review of the Competency Assessment (CA) records and interview with the General Supervisor (GS), the laboratory failed to perform the CA for two Testing Personnel (TP) in 2019. The finding includes: 1. Two out of five TP did not have a CA performed in the calendar year 2019. 2. The GS confirmed on 5/6/21 at 1: 30 pm that the CA was not performed .
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on surveyor review of Alfa Wassermann's Control Package Inserts (CPI) and interview with the General Supervisor (GS), the laboratory failed to follow CPI instructions for control ranges used on the Alera Alpha Wassermann - ACE analyzer for Alanine transferase (ALT) tests on the date of survey. The finding includes: 1. The GS stated the laboratory used CPI values for control ranges. 2. The CPI for AST was 37 - 57 but the laboratory used 33.6 - 46.4. 3. The laboratory did not verify the low

	end of the range which was below the CPI. 4. The GS confirmed on 5/6/21 at 1:30 pm that CPI instruction was not followed.
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 surveyor observation of the Quality Control (QC) reagents and interview with the General Supervisor (GS), the laboratory failed to put a new expiration date on the Coulter 4C-ES Cell QC reagents in use on the Beckman Coulter AcT diff 2 analyzer on the date of the survey. The findings include: 1. The Manufacturers Package Insert (MPI) stated "open vial stability is 31 days or open vial 20 times" 2. The laboratory did not put new expiration dates on the Coulter 4C-ES Cell QC after opening. 3. The GS confirmed on 5/7/21 at 12:00 pm the laboratory failed to put new expiration date on the QC reagents.
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 surveyor review of the Performance Specification (PS) records and interview with the General Supervisor (GS), the laboratory failed to ensure that all PS procedures were performed for Vitamin D testing on the Beckman Coulter (BC) Access 2 or were comparable to the manufacturers from October 2020 to the date of survey. The findings include: 1. The laboratory did not verify Accuracy and Patient Normal Range. 2. The laboratory assigned a Random Error Budget of 33.33% for Precision but BC recommended 16-25%. 3. There was no raw data on site to substantiate Linearity or Method Comparison results. 4. There was no documented review of Method Comparison results. 5. The GS confirmed on 5/6/21 at 11:15 am that not all PS were performed or comparable to the manufacturers .
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 surveyor review of Calibration Verification (CV) records and interview with the General Supervisor (GS), the laboratory failed to perform and document CV procedures at least once every six months for Hematology Testing on the Beckman Coulter AcT diff 2 analyzer in the calendar year 2019. The finding includes: 1. The laboratory performed CV December 2019 in the calendar year 2019. 2. There was no documented evidence that CV was performed every six months. 3. The GS confirmed on 5/7/21 at 11:30 am CV was not performed every six months. 35471 b. Based on lack of CV records and interview with the GS, the laboratory failed to perform and document CV procedures at least once every six months for routine chemistry tests performed on the Alera Alfa Wassermann - ACE analyzer from 3/15/18 to the date of survey. The GS confirmed on 5/6/21 at 1:50 pm that CV was not performed every six months for tests performed on the ACE analyzer.
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 surveyor review of the Quality Control (QC) records and interview with General Supervisor (GS), the laboratory failed to perform and document two levels of external controls on each day of patient testing for Immunodot Antinuclear Antibody (ANA) tests from 3/15/18 to the date of the survey. The findings include: 1. The laboratory reported ANA results but there was no documented evidence that QC was performed every day of patient testing. 2. The laboratory performed approximately 5-12 ANA tests per month 3. The GS confirmed on 5/6/21 at 10:20 am that two levels of QC were not run each of patient testing.
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 surveyor review of the Procedure Manual (PM) and interview with the General Supervisor (GS), the laboratory failed to establish a procedure for verifying manually entered results from 3/15/18 to the date of survey. The GS confirmed on 5/6 /21 at 1:30 pm that the laboratory did not have the procedure mentioned above.
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 surveyor review of the Performance Specification (PS) records and interview with the General Supervisor (GS), the Laboratory Director (LD) failed to ensure that PS procedures for Vitamin D tests performed on the Beckman Coulter Access 2 analyzer were adequate from October 2020 to the date of survey. The findings include: 1. There was no documented evidence Accuracy and Patient Normal Range were verified. 2. There was no raw data found to substantiate linearity and method comparison results. 3. Method Comparison results were not reviewed 3. The GS confirmed on 5/6/21 at 2:00 pm that PS records were not adequate.
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 lack of a Quality Assessment (QA) program and interview with the General Supervisor (GS), the Laboratory Director failed to ensure that a QA program was established from 3/15/18 to the date of survey. The GS confirmed on 5/6/21 at 2:15 pm that the laboratory did not have a QA program. Note: This deficiency was sited in prior survey performed on 3/15/18. Plan of Correction received stated QA program would be established.