Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D0677093	03/15/2018
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 Testing Personnel (TP), the laboratory failed to perform CA correctly on seven out of seven TP in the calender years 2016 and 2017. The findings include: 1. The laboratory did not document when testing personnel were observed, what records were reviewed and how assessment was done on CA for waive tests. 2. The laboratory did not perform CA on seven of seven TP for non waive tests in 2016 and 2017. 3. The TP # 1 listed on CMS form 209 confirmed on 3/15/18 at 10:20 am that the CA procedure was not performed correctly.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: a) Based on surveyor review of the Procedure Manual (PM), work records and interview with the Testing Personnel (TP), the laboratory failed to follow "Verification of Instrument/Manual Calculation"(VIMC) procedure in 2016 and 2017.

	The finding includes: 1. The VIMC procedure stated to verify laboratory information system twice a year but the laboratory did only once. 2. The TP # 1 listed on CMS form 209 confirmed on 3/15/18 at 12:45 PM that VIMC procedure was not followed. b) Based on surveyor review of VIMC procedure and interview with the TP, the laboratory did not include Manual Test (MT) verification in the procedure from 1/12 /16 to the date of survey. The TP # 1 confirmed on 3/15/18 that MT verification was not in procedure. c) Based on surveyor review of the PM, Quality Control (QC) records and interview with the TP, the laboratory failed to follow the Control Lot Verification procedure from 1/12/16 to the date of the survey. The findings include: 1. The PM stated to test the new lot in parallel with the old lot once a day for a minimum of three days. 2. A review of QC lot verification performed on Ace Alera controls revealed the new lot number was run one time before use. 3. The TP # 1 listed on CMS form 209 confirmed on 3/15/18 at 2:45 pm the PM was not followed d) Based on surveyor review of the PM and interview with the TP the laboratory failed to have a written procedure on performance and acceptance of Performance Specifications (PS) performed on new analyzers from 1/12/16 to the date of the survey. The TP # 1 listed on CMS form 209 confirmed on 3/15/18 at 2:55 pm above procedure was not in the PM. 35471
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 surveyor review of the Quality Control (QC) records, Manufacture Package Insert (MPI), QC material, and interview with the Testing Personnel (TP), the laboratory used expired QC material for all Routine Chemistry tests performed on the Beckman Access 2 (BA2) analyzer and Endocrinology tests performed on the Ace Alera Analyzer (AAA) from February 2018 to the date of survey. The findings include: 1. The MPI for Lyphochek Immunoassay Plus Control (LIPC) material stated reconstituted QC stored at 2 to 8 Celsius (C) expired after seven days for all analytes with the exception of Prostate Specific Antigen (PSA) which expired three days after reconstituting. 2. LIPC Lot 40343 was reconstituted 2/21/18 expired on 2/28/18 and Lot 40341 and 40342 was reconstituted on 2/28/18 and expired on 3/6/18. 3. Approximately 180 patients were run with expired QC. 4. The MPI for Gemcal Reference Serum (GRS) used on the AAA stated reconstituted QC stored at 2 to 8 C expired as follows: a. Direct and Total Bilirubin - 2 days. b. Triglycerides - 4 days. c. All other Analytes - 5 days. 5. GRS Lot 928UECM were reconstituted on 2/28/18 and 3/6/18 expired on 3/2/18 and 3/8/16 respectively. 6. Approximately 200 patients were run with expired QC. 7. The TP #1 on CMS form 209 confirmed on 3/15/18 at 1:45 pm that the laboratory used expired QC material.
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 Performance Specification (PS) records and interview with the Testing Personnel (TP), the laboratory failed to verify PS for Endocrinology and Routine Chemistry (RC) performed on the Beckman Access 2 (BA2) and Ace Alera (AA) analyzer respectively were adequate from October 2017 to the date of survey. The findings include: 1. Linearity was not performed on Thyroid Uptake performed on the BA2. 2. Accuracy was not performed on RC tests performed on the AA. 3. The TP #1 listed on CMS form 209 confirmed on 3/15/18 at 11:15 am that the PS records were not adequate.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(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-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (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 the Testing Personnel (TP), the laboratory failed to verify that the assayed QC materials were within the acceptable ranges before they were put into use for analytes performed on the AcT Diff 2 analyzer from July 2017 to 3/8/18. The finding includes: 1. The laboratory used three lots between that time and none of them were verified. 2. The TP #1 listed on CMS form 209 confirmed on 3/15/18 at 1:00 pm that the laboratory did not verify QC materials for analytes performed on AcT Diff 2 analyzer.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

	This STANDARD is not met as evidenced by: a) Based on surveyor review of the Quality Control (QC) Lot Verification (LV) and interview with the Testing Personnel (TP), the laboratory did not document Corrective Action (CA) taken when Chemistry Controls on the Ace Alera (AA) analyzer were out of range for LV on 1/19/18. The findings include: 1. There was no documented evidence of CA taken when Lot 1213UNCM and 937UECM LV was out of range as follows: a. QC Level 1 - Alanine aminotransferase (ALT) and Blood Urea Nitrogen (BUN) b. QC Level 2 - BUN 2. The above control was put in service on 1/19/18. 3. Approximately 15 to 20 patients were run per day on the AA. 4. The TP #1 listed on CMS form 209 confirmed on 3/15/18 at 2:10 pm that corrective action was not taken on out of range controls. b) Based on surveyor review of the Levy Jennings (LJ) charts and interview with the TP, the laboratory failed to document CA when AA QC fell on the same side of the mean for more than 10 days from 1/2/18 to 1/31/18. The findings include: 1. The review of Levy Jennings (LJ) charts for Lot 1213UNCM and 937UECM LV revealed consecutive control results on the same side of the mean for the following parameters: a. Level 1- Aspartate aminotransferase (AST) and Glucose - 16 days, Blood Urea Nitrogen (BUN) - 14 days and Alanine aminotransferase (ALT) - 11 days. b. Level 2 - ALT and Alkaline Phosphatase (ALP) - 16 days, BUN - 15 days, AST- 14 days. 2. The laboratory ran controls 16 days in January. 3. There were no February LJ charts for review. 4. The TP #1 confirmed on 3/15/18 at 2:00 pm that the laboratory didn't take CA.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: a) Based on the surveyor review of the Final Report (FR) and interview with the Testing Personnel (TP), the laboratory failed to have a source for Reference Intervals (RI) for Endocrinology tests performed on the Beckman Access 2 from May 2017 to the date of the survey. The TP #1 listed on CMS confirmed on 3/15/18 at 2:30 pm that the laboratory did have a source for RI reported on FR. b) Based on surveyor review of the Manufacturers Package Insert (MPI), FR and interview with the TP, the laboratory failed to ensure Normal Reference Intervals (RI) were correct on the FR for Routine Chemistry tests performed on the Ace Alera from 1/12/16 to the date of the survey. The findings include: 1. RI were as follows: a. Alkaline Phosphatase- the MPI RI was 44-143 but the RI on FR was 39-117. b. Total Bilirubin- the MPI RI was 0.3-1.2 but the RI on FR was 0.2-1.2. c. Aspartate aminotransferase (AST) the MPI RI was 7-31 but the RI on FR was 5-34. d. Carbon Dioxide (CO2) - the MPI RI was 23-29 but the RI on FR was 21-31. e. Glucose - the MPI RI was 74-106 but the RI on FR was 70-105. 2. The TP #1 confirmed on 3/15/18 at 2:15 pm that the laboratory failed to have the correct RI on the FR.
D6017	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(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)(4)(ii) Ensure that results are returned within the timeframes established by the proficiency testing program. This STANDARD is not met as evidenced by: Based on surveyor review of the Profciency Testing (PT) records and interview with the and Laboratory Director (LD) and Testing Personnel (TP), the LD failed to ensure that 'Additional Analytes' for Antinuclear Antibody tests were reported in all three American Proficiency Institute (PT) events in 2016 and 2017. The LD confirmed on 3 /15/18 at 1:30 pm that Additional test were not reported.
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 Testing Personnel (TP), the Laboratory Director failed to ensure that a QA program was established from 1/12/16 to the date of survey. The TP #1 listed on CMS form 209 confirmed on 3/15/18 at 3:15 pm that the laboratory did not have a QA program.
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 surveyor review of the Procedure Manual and interview with the Testing Personnel (TP), the Laboratory Director failed to establish a Competency Assessment (CA) procedure with the required elements from 1/12/16 to the date of the survey. The TP # 1 listed on the CMS form 209 confirmed on 3/15/18 at 11:00 am that a CA procedure was not established.

D6072	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(3) Each individual performing moderate complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed. This STANDARD is not met as evidenced by: Based on surveyor review of the Instrument Calibration Log (ICR) and interview with the Testing Personnel (TP), the TP failed to document calibration on the Ace Alera Chemistry analyzer from January 2018 to the date of survey. The findings include: 1. A review of the CL revealed calibrations were missed as follows: a. Direct Bilirubin - Calibration due every 30 days last calibration was performed 1/29/18. b. Blood Urea Nitrogen (BUN) - Calibration due every 7 days. Calibration was performed 1/3/18, 1 /18/18, 2/26/18 and 3/9/18. c. Creatinine - Calibration due every 2 days. Calibration was performed 1/24/18, 1/29/18, 2/20/18, 2/26/08, 3/1/18, 3/9/18 and 3/13/18. d. High Density Lipoprotein (HDL) - Calibration due every 30 days last calibration was performed 1/29/18. 2. The TP #1 listed on CMS form 209 confirmed on 3/15/18 at 11: 50 am that the laboratory did not document Calibration activities.
D6074	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(5) Each individual performing moderate complexity testing must be capable of identifying problems that may adversely affect test performance or reporting of test results and either must correct the problems or immediately notify the technical consultant, clinical consultant or director. This STANDARD is not met as evidenced by: Based on surveyor review of the Levy Jennings (LJ) records and interview with the Testing Personnel (TP), the TP failed to identify problems that may affect test performance by not reviewing and evaluating trends and/or shifts for Routine Chemistry tests performed on the Ace Alera analyzer from November 2017 to the date of the survey. The TP #1 listed on CMS form 209 confirmed on 3/15/18 at 2:45 pm that trends and shifts were not reviewed.