Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D2096452	04/23/2024
Name of Provider or Supplier	**Street Address, City, State**	
Cliffside Labs Dba Valgen Labs	7 Deer Park Drive, Monmouth Junction, 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
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the General Supervisor (GS), the laboratory failed to evaluate all ungraded scores for PT event DAI-A-2024 performed with the College of American Pathologists (CAP). The findings include: 1. Specimen DAI-03 for Specific Gravity Qualitative was resulted as "Abnormal" and was graded as "See Note 26". 2. The method interpreation (educational) by Microgenics DRI had a 60.2% frequency for "Abnormal" by peer group analysis. 3. The GS stated on the PT records "educational codes 26 were reviewed with >80% consensus on 3/28/24 for PT event DAI-A-2024. 4. There was no documented evidence for self-evaluation performed for specimen DAI-03 Specific Gravity Qualitative which did not have a >80% consensus. 5. The GS confirmed on 4 /23/24 at 1:20 pm, the laboratory failed to evaluate all ungraded PT scores.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by:

	Based on surveyor review of the Proficiency Testing (PT) records, Procedure Manual (PM) and interview with the General Supervisor (GS), the laboratory failed to have a mechanism for its PT results provided by the College of American Pathologists (CAP), which includes a review of its actual PT results against the PT provider's participant summary results for PT events from 4/1/23 to 4/26/24 The findings include: 1. CAP states "Educational PT/EQA challenges are designated with an evaluation code 26. These challenges are not formally graded, and laboratories should utilize data in the participant summary report to perform a self-evaluation." 2. The laboratory failed to have a procedure for self-evaluation for ungraded PT results which includes acceptability and rejection criteria. 3. The GS confirmed on 4/23/24 at 1:45 pm, the laboratory failed to have a procedure for self-evaluation for ungraded PT results provided by CAP.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM), Instrument Correlation Records (ICR) and interview with the General Supervisor (GS), the laboratory failed to follow their Instrument to Instrument Verification Procedure (IIVP) that defines the relationship between Routine Chemistry and Toxicology test results performed on the two Beckman Coulter AU680 analyzers from 3/22/24 to 4/26/24. The finding includes: 1. The IIVP states "select 2 previously processed patient samples (preferably a negative and positive sample). Follow the procedure for running samples and the selected samples on both instruments." 2. There was only one previously processed patient sample ran and not two samples as it states for the AU680 IIVP performed on 3 /22/24. 3. The GS confirmed on 4/26/24 at 1:30pm, the laboratory failed to follow the IIVP.
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 the lack of Training Records (TR) and interview with the General Supervisor (GS) the Laboratory Director (LD) failed to ensure that all Testing Personnel (TP) received the appropriate training for the type and complexity of the services offered from 1/15/24 to 4/23/24. The findings include: 1. Two out of two TP listed on the CMS 209 form failed to have training records for using the Beckman Coulter AU680 analyzers. 2. The GS confirmed on 4/23/24 at 1:35 pm, the LD failed

	to ensure TP had appropriate training for the type and complexity of the services offered.