Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D2096452	10/20/2022
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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on surveyor review of the Patient Work Records (PWR) and interview with the General Supervisor (GS), the laboratory failed to documenting all analytic systems activities for Toxicology and Routine Chemistry from 7/11/19 to the date of the survey. The finding includes: 1. From a random sample of five patients PWR 3 out of 5 did not have Quality flag, Sample post dilution/concentration, or Analysis flag headings. 2. The GS confirmed on 10/20/22 at 11:40 am the laboratory failed to documenting all analytic systems activities.
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: Based on surveyor review of the laboratory records, Procedure Manual (PM) and interview with the General Supervisor (GS) the laboratory failed to establish a written

	maintenance procedure for the Horiba ABX Pentra 400 from 7/11/19 to the date of the survey. The GS confirmed on 10/20/22 at 11:30 am that the laboratory did not establish a written maintenance procedure.
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 the Horiba ABX Pentra 400 Analyzers Reagent Manufacturers Package Insert (MPI) and interview with the General Supervisors (GS), the laboratory failed to follow the MPI for Specimen Stability from 7/11/19 to the date of survey. The findings include: 1) The MPI for reagent DRI Barbiturate Assay states in "Specimen Collection and Handling"specimens "may be placed into a secure refrigeration unit at 2-8C for up to 7 days. For longer storage prior to analysis or for sample retention after analysis, urine specimens may be stored at -20C." 2) GS stated "specimens are received on ice packs" 3) Patient # 10630 Acc# 17319 collected on 10/6/22 was received by the laboratory 10/18/22. 4) Patient # 10630 Acc# 17319 was run and reported 10/18/22 five days after its stability date. 5) The GS confirmed on 10/20/22 at 12:30 pm the MPI 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 review of Manufactures Package Inserts, observation of the Quality Control material, and interview with the General Supervisor (GS), the laboratory failed to put expiration dates on MAS Drugs Of Abuse Total Control material run on the Horiba ABX Pentra 400 on the date of survey. The GS confirmed on 10/20/22 at 12:00 pm the laboratory failed to put expiration dates on the control material.
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: Based on surveyor review of the Patient Work Records (PWR) and interview with the General Supervisor (GS), the laboratory failed to perform corrective action when Urine Creatinine results flagged "C" for the Horiba ABX Pentra 400 analyzer in October 2022. The findings include: 1. PWR flagged "C" for Urine Creatinine tests run and reported on 10/7/22. 2. There was no documented evidence corrective action was taken. 3. The GS confirmed on 10/20/22 at 12:10 pm that corrective action was not performed.
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 surveyor review of the Procedure Manual (PM) and interview with the General Supervisor (GS), the laboratory failed to establish written policies and procedures to monitor, assess and correct problem identified in the analytic system quality assessment from 7/11/19 to the date of survey. The findings include: 1. The laboratory did not have a corrective action procedure for Flagged patient results. 2. The GS confirmed on 10/20/22 at 11:10 am that they have no written policy for the above mentioned procedure.
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 the Final Report (FR) and interview with the General Supervisor (GS), the laboratory failed to ensure that FR had accurate information from 7/11/19 to the date of survey. The findings include: 1. There was no Test Report Date. 2. The reference ranges for Toxicology tests did not have a unit of measurement. 3. There was no Specimen source. 4. The GS on 10/20/22 at 11:00 am that the laboratory failed to ensure that FR had accurate information.