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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 31D2096452 | (X3) Date Survey Completed 07/11/2019 |
| Name of Provider or Supplier Cliffside Labs DbA Valgen Labs | Street Address, City, State 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 |
|---------------------------|---|
| D3037 | <p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4)</p> <p>Proficiency testing records. Retain all proficiency testing records for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of Proficiency Testing (PT) records and interview with the Testing Personnel (TP), the laboratory failed to retain all PT records performed with the American Proficiency Institute for event 2 of 2018. The TP confirmed on 7/11/19 at 10:00 am that the laboratory failed to retain all PT records.</p> |
| D5401 | <p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM) and interview with the Testing Personnel (TP), the laboratory failed to follow the "General Policies for Quality Control" (QC) procedure for urine drug screening tests from 8/24/17 to the date of the survey. The finding includes: 1. The PM stated "new QC will be validated prior to use" but there was no documented evidence new lots of QC were run before using. 2. The TP confirmed 7/11/19 at 10:30 am that the laboratory did not follow the PM. b. Based on surveyor review of the PM and interview with the TP, the laboratory failed to follow the "Corrective Action" (CA) procedure for urine Toxicology tests from 8/24/17 to the date of the survey. The finding includes: 1. The PM stated "CA</p> |

from testing problems are logged in a CA file or notebook" but there was no documented evidence of a CA file or notebook. 2. The TP confirmed 7/11/19 at 10:40 am that the laboratory did not follow the PM.

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 Manufacturer's Package Insert (MPI), Final Reports (FR), and interview with the Testing Personnel (TP), the laboratory failed to follow the manufacturer's instruction for resulting Urine Creatinine (UC) tests from 8/24/17 to the date of survey. The finding includes: 1. The MPI stated the intended use of the UC test was quantitative but the laboratory reported results as Pass or Fail on the FR. 2. The TP confirmed on 7/11/19 at 12:10 pm that the laboratory did not follow the MPI.

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 lack of Calibration Verification (CV) records and interview with the Testing Personnel (TP), the laboratory failed to perform and document CV procedures at least once every six months for urine creatinine performed on the Horiba Pentra 400 analyzer from 8/24/17 to the date of the survey. The TP confirmed on 7/11/19 at 12:20 pm CV was not performed every six months.

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 Final Report (FR) and interview with the Testing Personal (TP), the laboratory failed to identify problems on the FR for pH in the Validity Panel from 8/24/17 to the date of the survey. The finding includes: 1. The laboratory did not use correct terminology for flagging pH results. 2. The TP confirmed on 7/11/19 at 11:45 am that the laboratory did not identify problems on the final report.