

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 13D0666466	(X3) Date Survey Completed 04/26/2018
Name of Provider or Supplier Vandal Health Clinic Laboratory	Street Address, City, State 831 Ash St, Moscow, ID	
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
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: Based on proficiency testing (PT) record review and an interview with the laboratory technologist, the laboratory failed to maintain the Wisconsin State Laboratory of Hygiene (WSLH) complete blood count (CBC) PT sample results from the Beckman Coulter AcT Diff 2 for the second and third events in 2017. Findings: 1. A PT record review from WSLH revealed the laboratory failed to retain the CBC sample results from the Beckman Coulter AcT Diff 2 analyzer for the 2017 second and third testing events. 2. An interview on April 26, 2018 at 9:30 AM, with the laboratory technologist, confirmed the WSLH PT CBC sample result forms failed to be available at the time of survey.</p>
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p>

This STANDARD is not met as evidenced by:
Based on a record review and an interview with the laboratory technologist, the laboratory failed to verify the accuracy of potassium hydroxide (KOH)/wet mounts and urine sediment exams at least twice annually since the last survey on June 1, 2016. Findings: 1. A record review revealed the laboratory failed to document the accuracy of KOH/wet mounts and urine sediment exams, at least twice annually since the last survey. 2. An interview on April 26, 2018 at 9:20 AM, with the laboratory technologist, confirmed the laboratory failed to document the accuracy of KOH/wet mounts and urine microscopic exams at least twice annually.

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 record review and an interview with the laboratory technologist, the laboratory failed to verify the performance of the Beckman Coulter AcT Diff 2 complete blood count (CBC) analyzer after the lab moved the instrument to another location during the summer of 2017 while the lab was closed, and then returned to the of University Health Center in August 2017. Findings: 1. A record review of the AcT Diff 2 calibration records revealed the laboratory failed to verify the performance of the analyzer after moving the analyzer off-site and then returning it to the laboratory. 2. An interview on April 26, 2018 at 11:30 AM, with the laboratory technologist, confirmed the laboratory moved the analyzer to another location during the summer of 2017 and returned the analyzer to the University Health Center in August of 2017.

D5787

TEST RECORDS
CFR(s): 493.1283(a)

The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s).

This STANDARD is not met as evidenced by:
Based on a record review and an interview with laboratory technologist, the laboratory failed to identify the identity of the personnel performing complete blood counts (CBCs) during the dates reviewed in 2017. Findings: 1. A record review of patients during September 14, 2017 and October 24, 2017 revealed the testing personnel who performed CBCs on patient samples were not identified. 2. An

interview on April 26, 2018 at 12:00 PM, with the laboratory technologist, confirmed the laboratory testing personnel performing CBCs on patients were not identified.

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 a record review of final patient reports and an interview with the laboratory technologist, the laboratory failed to indicate the address of their laboratory and the name and address of the reference laboratory where tests were reported on patients for the period reviewed between September 2017 through October 2017. Findings: 1. A review of patient laboratory test reports revealed the address of the laboratory and the name and address of the reference laboratory where tests were performed failed to be included on the patient's test reports. 2. An interview on April 26, 2018, at 12:15 PM, with the laboratory technologist, confirmed the address of the laboratory and the name and address of the reference laboratory failed to be indicated on patient reports.

D6046

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:
Based on a record review of personnel competency assessments and an interview with the laboratory technologist, the technical consultant failed to establish and follow procedures to assess the competency of testing personnel since the last survey on June 1, 2016. Findings: 1. A review of personnel documents and laboratory procedures and policies revealed the laboratory failed to establish a policy to assess the competency of 3 mid-level practitioners and 2 providers performing potassium hydroxide/wet mounts and urine sediment examinations since the last survey. 2. An interview on April 26, 2018, at 9:45 AM, with the laboratory technologist, confirmed the laboratory failed to establish in writing a policy to assess and perform competencies for the practitioners and providers.