Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	13D0520880	09/17/2018
Name of Provider or Supplier	**Street Address, City, State**	
Ammon Medical And Urgent Care	3456 E 17th St #125, Ammon, 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
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on a record review and an interview with the laboratory lead, the laboratory failed to test the American Proficiency Institute (API) proficiency testing (PT) samples for complete blood count (CBC) analysis by personnel who perform patient testing since the last survey on September 28, 2016. Findings: 1. A review of PT records from API revealed the laboratory failed to rotate the testing of CBC samples from API by personnel who routinely perform testing in the laboratory since the last survey. 2. An interview on September 17, 2018 at 11:15 AM, with the laboratory lead, confirmed the laboratory failed to test the CBC proficiency samples by personnel who routinely perform patient CBC analysis since the last survey.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on proficiency testing (PT) record review and an interview with the laboratory manager, the laboratory failed to document the review and corrective actions for an unsatisfactory score for red blood cells in the specialty of hematology for the American Proficiency Institute (API) proficiency testing (PT) program 2017 event 3. Findings: 1. A review of PT results from API for the 2017 event 3 revealed the

	laboratory failed to document the review and corrective actions for unsatisfactory red blood cell results. 2. An interview on September 17, 2018 at 11:30 AM, with the laboratory manager, confirmed the laboratory failed to document the evaluation and corrective actions for an unsatisfactory red blood cell score performed during the 2017 event 3.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on a procedure manual review and an interview with the laboratory manager, the laboratory failed to include the steps to take for corrective actions when control or calibration material fails to meet the laboratory's specified requirements, panic values, interfering substances or limitations actions, and steps to take when the Cell-Dyn Emerald complete blood count (CBC) analyzer becomes inoperable since the last survey on September 28, 2016. Findings: 1. A review of the laboratory's procedure manual revealed the procedure failed to include panic values for patient CBC results, corrective actions to take when quality controls or calibrations fail, and instructions to take when the Cell-Dyn analyzer becomes inoperable. 2. An interview on September 17, 2018 at 11:45 AM, with the laboratory manager, confirmed the laboratory's procedure manual for performing CBCs failed to include all requirements for testing.
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 a record review and an interview with the laboratory lead, the laboratory failed to follow the manufacturer's instructions for troubleshooting patient samples

	when errors or flags are generated by the Cell-Dyn Emerald complete blood count (CBC) analyzer since the last survey on September 28, 2016. Findings: 1. A review of patient CBC results from April 4 through 12, 2018 revealed the laboratory failed to follow the manufacturer's instructions to perform troubleshooting procedures when the instrument flags the sample from interference or limitations in sample analysis. 2. An interview on September 17, 2018 at 12:05 PM, with the laboratory lead, confirmed the laboratory failed to follow the manufacturer's instruction for troubleshooting sample analysis and did not have a procedure for actions to take when the analyzer flags a sample.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: Based on a record review and an interview with the laboratory manager, the laboratory failed to document unscheduled maintenance activities and corrective actions for the Cell-Dyn Emerald complete blood count (CBC) analyzer since the last survey on September 28, 2016. Findings: 1. A record review revealed the laboratory failed to document trouble shooting and corrective actions activities on for unscheduled maintenance performed on the hematology analyzer in the lab since the last survey. 2. An interview on September 17, 2018 at 12:00 PM, with the laboratory manager, confirmed the laboratory failed to document unscheduled maintenance activities for the analyzer.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on a record review and an interview with the laboratory manager, the laboratory failed to perform and document calibration procedures at least once every 6 months or as indicated by the manufacturer for the Cell-Dyn Emerald complete blood count (CBC) analyzer between December 2015 and March 2018. Findings: 1. A

	record review of calibration reports for the Cell-Dyn Emerald analyzer revealed the laboratory failed to perform and document calibration activities at least once every 6 months for hematology analyzer or when indicated by the manufacturer. 2. An interview on September 17, 2018, at 12:40 PM, with the laboratory manager, confirmed the laboratory failed to perform and document calibration procedure activities for the hematology 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: Based on a record review and an interview with the laboratory manager, the laboratory failed to document corrective actions for the Cell-Dyn Emerald hematology test system since the last survey on September 28, 2016. Findings: 1. A review of quality control records from the Cell-Dyn hematology analyzer revealed the laboratory failed to document trouble shooting and corrective actions when laboratory personnel tested normal and high levels of external quality control materials 20 times and low level 3 times for the day reviewed on April 8, 2018. 2. An interview on September 17, 2018, at 11:35 AM, with the laboratory manager, confirmed the laboratory failed to document corrective actions for when external quality controls for the hematology analyzer failed to be within the manufacturer's range of acceptability.
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 a record review and an interview with the laboratory manager, the laboratory director failed to assure the quality assessment program for the laboratory meets the CLIA requirements since the last survey on September 28, 2016. Findings: 1. A record review revealed the laboratory director failed to identify and correct problems in testing complete blood counts external quality controls. 2. A record review of patient complete blood count results revealed the laboratory testing personnel failed to follow the manufacturer's instructions for troubleshooting patient results with flags from the instrument. 3. A review of proficiency testing records

	revealed the laboratory director failed to sign the attestation statements from American Proficiency Institute for the 2018 event 1 and 2017 event 2. 4. An interview on September 17, 2018, at 12:15 PM, with the laboratory manager, confirmed the laboratory director failed to identify, document, and correct problems for the Cell-Dyn hematology analyzer.
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 documents and an interview with the laboratory manager, the technical consultant who is the laboratory director failed to evaluate the competency for 1 out of 7 testing personnel performing complete blood counts (CBC) since September 28, 2016. Findings: 1. A review of personnel documents revealed the technical consultant failed to evaluate the competency for 1 out of 7 testing personnel performing CBCs on the Emerald Cell-Dyn hematology analyzer since the last survey. 2. An interview on September 17, 2018 at 11:10 AM, with the laboratory manager, confirmed the technical consultant failed to evaluate the competency for one testing personnel.
D6051	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(v) The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. This STANDARD is not met as evidenced by: Based on a record review of personnel documents and an interview with the laboratory lead, the technical consultant who is the laboratory director failed to evaluate the assessment of test performance through external proficiency testing or blind testing as part of the competency assessment for 7 out of 7 testing personnel since the last survey on September 28, 2016. Findings: 1. A review of the laboratory's Skills Verification of Laboratory Tests document used to record testing personnel competency assessments, revealed the documents failed to include the evaluation of external proficiency testing or blind testing through previously analyzed samples as part of the evaluation. 2. An interview on September 17, 2018 at 11:10 AM, with the laboratory manager, confirmed the laboratory assessment worksheets failed to record the evaluation of external blind testing as part of the competency assessment for personnel since the last survey.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

	This STANDARD is not met as evidenced by: Based on a record review of personnel documents and an interview with the laboratory manager, the technical consultant who is the laboratory director failed to evaluate employee competency at least semiannually during the first year of patient testing on the Emerald Cell-Dyn hematology analyzer since July 2017. Findings: 1. A record review of competency evaluation documents revealed 1 out of 7 testing personnel listed on the CMS-209 Personnel Report form failed to have competency assessment performed at least semiannually during the first year of patient testing on the hematology analyzer. 2. An interview on September 17, 2018 at 11:15 AM, with the laboratory manager, confirmed the technical consultant failed to perform competency at least semiannually on 1 testing personnel since 2017.