Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 13D0521251	**(X3) Date Survey Completed** 10/02/2018
Name of Provider or Supplier Adams County Health Center	**Street Address, City, State** 205 N Berkley St, Council, 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 proficiency testing (PT) review and an interview with the laboratory lead, the laboratory failed to rotate the testing of American Association of Bioanalysts (AAB) proficiency testing (PT) samples for complete blood counts (CBCs) by the testing personnel who routinely perform patient testing since the last survey on January 26, 2017. Findings: 1. A review of AAB PT records revealed the laboratory failed to rotate the CBC PT samples by all testing personnel who perform patient testing since the last survey. 2. An interview on October 2, 2018 at 9:35 AM, with the laboratory lead, confirmed the laboratory failed to rotate the CBC proficiency samples from AAB by testing personnel who routinely test patient CBCs since the last survey.
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS

	may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on a proficiency testing (PT) review, the laboratory failed to successfully participate in proficiency testing for the analyte hematocrit (HCT). Refer to D2130.
D2130	HEMATOLOGY CFR(s): 493.851(f) Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on a proficiency testing (PT) review and the laboratory's graded PT results from the American Association of Bioanalysts (AAB), the laboratory failed to achieve successful performance for the analyte hematocrit (HCT) in two out of three testing events. Findings: Analyte Year Event Score HCT 2018 1 60% HCT 2018 2 0%
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 a record review and an interview with the laboratory lead, the laboratory failed to retain the manufacturer's quality control assay reference sheets for the Horiba Pentra hematology analyzer since the last survey on January 26, 2017. Findings: 1. A review of the quality control records revealed the laboratory failed to retain the manufacturer's Minotrol quality control assay reference sheets since the last survey. 2. An interview on October 2, 2018 at 9:15 AM, with the laboratory lead, confirmed the testing personnel failed to retain the quality control assay sheets for the hematology analyzer.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by:

	Based on a record review of personnel documents and the procedure manual, and an interview with the laboratory lead, the laboratory failed to establish and follow written policies and procedures to evaluate the competency of testing personnel performing complete blood counts since the last survey on January 26, 2017. Findings: 1. A review of competency assessment documents for the testing personnel and a review of the laboratory procedures and policies, revealed the laboratory failed to establish in writing and document the competency evaluations for 6 out of 6 testing personnel listed on the CMS-209 Personnel Report form by a qualified technical consultant. 2. An interview on October 2, 2018 at 9:15 AM, with the laboratory lead, confirmed the laboratory failed to establish and follow written policies and procedures to assess the competency of testing personnel.
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 lead, 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, pediatric ranges, and steps to take when the Horiba Pentra complete blood count (CBC) analyzer becomes inoperable since the last survey on January 26, 2017. Findings: 1. A review of the laboratory's procedure manual revealed the procedure failed to include panic values for patient CBC results, pediatric ranges for analytes, 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 October 2, 2018 at 10:15 AM, with the laboratory lead, confirmed the laboratory CBC procedure failed to include all requirements for performing CBCs on patient specimens.
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 lead, the laboratory failed to indicate the date tests were performed and the name and the address of the reference laboratory where complete blood counts and manual differential tests were reported on patients for the period since the last survey on January 26, 2017. Findings: 1. A review of patient laboratory test reports revealed the date complete blood counts and manual differentials were performed 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 October 2, 2018 at 9:15 AM, with the laboratory lead, confirmed the date and the name and address of the reference laboratory failed to be indicated on patient laboratory reports.
D6035	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 (a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity

	testing in all specialties and subspecialties of service. This STANDARD is not met as evidenced by: Based on a record review and an interview with the laboratory director, the laboratory director who was listed as the technical consultant failed to qualify for the position based on the education, training, and experience requirements for the position since February 15, 2017. Findings: 1. A review of personnel documents for the laboratory director revealed the education, training, and experience requirements failed to be met for the technical consultant position. 2. An interview on October 2, 2018 at 9:15 AM, with the laboratory director, revealed the laboratory director failed to meet the requirements for the technical consultant position.
D6036	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413 The technical consultant is responsible for the technical and scientific oversight of the laboratory. This STANDARD is not met as evidenced by: Based on records review and an interview with the laboratory director, the laboratory director who was listed as the technical consultant, failed to provide technical and scientific oversight for the testing of complete blood counts since February 15, 2017. Findings: 1. A review of quality control documents, calibration documents, and general laboratory systems revealed the laboratory director who was listed as the technical consultant failed to monitor quality control data, calibration activity, and general laboratory function in the specialty of hematology. 2. An interview on October 2, 2018 at 9:15 AM, with the laboratory director, confirmed the laboratory director failed to provide the technical oversight for the laboratory.