Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	13D2119538	07/24/2018
Name of Provider or Supplier	**Street Address, City, State**	
Aop Dba Summit Cancer Center-Post Falls	1641 E Polston Ave Ste 102, Post Falls, 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) record review and an interview with the laboratory lead, the laboratory failed to rotate the American Association of Bioanalysts (AAB) hematology test events through all testing personnel since the AAB 2017 quarter 1 event. Findings: 1. A record review of PT documents from AAB revealed the laboratory lead was the only testing personnel performing the hematology PT events. 2. An interview on July 25, 2018 at 3:00 PM, with the laboratory lead, confirmed the laboratory failed to rotate the PT events through all the testing personnel listed on the CMS-209 Personnel Report form.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (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.

	This STANDARD is not met as evidenced by: Based on a proficiency testing (PT) record review and an interview with the laboratory lead, the laboratory director failed to sign the American Association of Bioanalysts (AAB) hematology test attestation statements since 2017 quarter 1 event. Findings: 1. A record review of PT documents from AAB revealed the laboratory director failed to sign the attestation statements for testing performed in the specialty of hematology since the 2017 quarter 1 event. 2. An interview on July 25, 2018 at 3: 00 PM, with the laboratory lead, confirmed the laboratory director failed to sign the attestation statements since 2017 quarter 1 through 2018 quarter 1.
D2128	HEMATOLOGY CFR(s): 493.851(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on a proficiency testing (PT) record review and an interview with the laboratory lead, the laboratory failed to document corrective actions for unsatisfactory platelet score of 60% for the American Association of Bioanalysts (AAB) 2018 quarter 1 event. Findings: 1. An AAB PT record review from 2018 quarter 1 event, revealed the laboratory received a score of 60% for platelets and failed to document any corrective actions for the failed analyte. 2. An interview on July 25, 2018 at 3:10 PM, with the laboratory lead, confirmed the laboratory failed to document corrective actions for the failed analyte.
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 review and an interview with the laboratory lead, the laboratory failed to include critical values for the Horiba ABX Micros hematology analyzer since the start of testing in October 2016. Findings: 1. A review of the procedure manual revealed the critical value policy failed to include the panic values for complete blood counts. 2. An interview on July 25, 2018 at 5:15 PM, with the laboratory lead, confirmed the laboratory failed to include critical values for complete blood counts.
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 an observation of the laboratory refrigerator and an interview with the laboratory lead, the laboratory testing personnel failed to write the expiration dates of the complete blood count (CBC) controls since October 2016. Findings: 1. An observation of the refrigerator in the laboratory on July 25, 2018 at 5:05 PM, revealed the Minitrol quality control materials for CBC testing was only documented with the open date of the reagents. 2. An interview on July 25, 2018 at 5:10 PM, with the laboratory lead, confirmed expiration dates were not identified on the control vial.
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 record reviews and an interview with the laboratory lead, the laboratory final reports failed to identify the name and address of the laboratory that performed laboratory tests and the dates tests were performed since October 2016. Findings: 1. A record review of final patient reports revealed the address of the laboratory performing complete blood counts was not indicated on the reports. 2. A record review of final patient reports revealed the final reports failed to include the name and address of the reference laboratory, the test performed, and date the test was performed since October 2016. 3. An interview on July 25, 2018 at 6:05 PM, with the laboratory lead, confirmed the laboratory's address, the reference laboratory's name

	and address, the test performed, and the date the test was performed was not identified on the patient final reports.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on record reviews and interviews with the laboratory lead, the laboratory director failed to provide overall management and direction for the laboratory since the start of testing in October 2016. Refer to D6021, D6029, D6030, and D6032.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on a record review of personnel documents and an interview with the laboratory lead, the laboratory failed to qualify 1 out 4 testing personnel to ensure that they meet the educational requirements to perform testing on the Horiba ABX complete blood count (CBC) analyzer since January 2017. Findings: 1. A review of personnel education documents revealed that 1 out of 4 testing personnel listed on the CMS-209 Personnel Report form failed to have their education evaluated before testing patient specimens. 2. An interview on July 25, 2018 at 3:05 PM, with the laboratory lead, confirmed the laboratory failed to have the education qualifications evaluated for 1 out of 4 testing personnel in 2017.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) 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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

	This STANDARD is not met as evidenced by: Based on a review of the procedure manual and an interview with the laboratory lead, the laboratory director failed to ensure that policies and procedures were established for monitoring the competency of 4 out of 4 testing personnel performing complete blood counts (CBCs) since the start of testing in October 2016. Findings: 1. A review of the laboratory's quality assurance plan revealed the laboratory failed to establish a procedure for assessing the competency of testing personnel listed on the CMS-209 Personnel Report form performing CBCs. 2. A review of personnel competency documents revealed biannual and annual assessments for the 4 testing personnel was not documented for 2016 and 2017. 3. A review of personnel competency documents revealed assessments for the 4 testing personnel was not performed by a qualified technical consultant. 4. An interview on July 25, 2018 at 3:15 PM, with the laboratory lead, confirmed the laboratory director failed to establish procedures for assessment of testing personnel performing CBCs.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) 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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on a record review and an interview with the laboratory lead, the laboratory director failed to specify in writing, the responsibilities and duties of the technical consultant and testing personnel engaged in the preanalytic, analytic, and postanalytic phases of testing since the start of testing in October 2016. Findings: 1. A review of the laboratory documents revealed the laboratory failed to specify in writing the responsibilities and duties of the technical consultant and the testing personnel. 2. An interview on July 25, 2018 at 3:30 PM, with the laboratory lead, confirmed the laboratory director failed to specify in writing the responsibilities for the technical consultant and testing personnel.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on record reviews, the laboratory failed to have a qualified technical consultant

	perform the responsibilities for the position at the time of survey on July 25, 2018. Refer to D6035, D6046, and D6053.
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 record reviews and an interview with the laboratory lead, the laboratory failed to employ a technical consultant who meets the education and experience qualifications to fulfill the role of technical consultant. Findings: 1. A review of personnel records revealed the laboratory lead failed to qualify as a technical consultant for the laboratory performing tests in hematology. 2. During the survey, the laboratory added an off-site consultant to the CMS-209 form, but failed to provide evidence of education to qualify as a technical consultant. 3. An interview on July 25, 2018 at 3:45 PM, with the laboratory lead, confirmed the laboratory failed to have a qualified technical consultant.
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 personnel records review and an interview with the laboratory lead, the laboratory failed to have a qualified individual perform competency assessments on the 4 testing personnel performing complete blood counts (CBCs) on the Horiba ABX Micros since the start of testing in October 2016. Findings: 1. A review of personnel records revealed the laboratory failed to have an individual qualified to be the technical consultant perform competency assessments on 4 out of 4 personnel listed on the CMS-209 Personnel Report form. 2. An interview on July 25, 2018 at 3:15 PM, with the laboratory lead, confirmed the laboratory failed to have a qualified individual perform competency assessments.
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 lead, the laboratory failed to assess employee competency at least semiannually during their first year of patient testing on the Horiba ABX Micro hematology analyzer used to test complete blood counts (CBCs) since October 2016. Findings: 1. A record review of personnel documents revealed 4 out of 4 testing personnel listed on the CMS-209 Personnel Report form, failed to have competency assessments performed at least semiannually during the first year of patient testing. 2. An interview on July 25, 2018 at 3:10 PM, with the laboratory lead, confirmed the laboratory failed to perform competency at least semiannually on 4 testing personnel since 2016.