Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	13D0646318	03/22/2018
Name of Provider or Supplier	**Street Address, City, State**	
Glenns Ferry Health Center Inc	120 Desert Sage Way, Mountain Home, 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	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 an interview with the laboratory manager and proficiency testing (PT) record review, the laboratory director failed to sign the attestation statements from the the American Association of Bioanalysts (AAB) for complete blood count (CBCs) and wet mounts in 2017. Findings: 1. An AAB PT document review revealed the laboratory director and testing personnel failed to sign the attestation statements for CBC and wet mount analytes for 2017. 2. An interview on March 22, 2018 at 9:40 AM, with the operation manager, confirmed the laboratory director and testing personnel failed to sign the PT attestation statements for 2017.
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 operation director, the laboratory failed to retain quality control results and patient test results printed from the QCB Star complete blood count (CBC) analyzer since the last survey on March 23, 2016 at both the Glenns Ferry Health Center and the Desert Sage Health Center in Mountain Home. Findings: 1. A record review of the QBC Star CBC print-outs for quality control and patient test results revealed the laboratory failed to retain quality control results and patient CBC results since the last survey at both the Glenns Ferry Health Center and the Desert Sage Health center in Mountain Home. 2. An interview on March 22, 2018 at 10:30 AM, with the operation manager, confirmed the testing personnel from both Health Centers failed to retain quality control results and patient test results printed from the QBC Star analyzer.
D5213	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1) The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program. This STANDARD is not met as evidenced by: Based on proficiency testing (PT) record review and an interview with the operation manager, the laboratory failed to evaluate their performance on the American Association of Bioanalysts (AAB) PT for complete blood counts (CBC), performed at Glenns Ferry Health centers and the Desert Sage Health Center in Mountain Home and Valley Health Center in Grand View, that was not graded during since 2016. Findings: 1. A record review of CBC PT results from AAB, revealed the leukocytes from the 2017 quarter 3 was not graded. 2. A record review of CBC PT results from AAB, revealed the leukocytes, hematocrit, and platelets from the 2017 quarter 2 was not graded. 3. A record review of CBC PT results from AAB, revealed the leukocytes was not graded and hematocrit the incorrect from the 2017 quarter 1. 4. A record review of CBC PT results from AAB, revealed the platelets from the 2016 quarter 3 was not graded. 5. An interview on March 22, 2018 at 9:30 AM, with the operation manager, confirmed the laboratory failed to evaluate their performance on ungraded analytes since the last survey.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) 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. This STANDARD is not met as evidenced by: Based on a record review and an interview with the operation director, the laboratory failed to verify the accuracy of potassium hydroxide (KOH) at least twice annually in 2017. This is a repeat deficiency from the March 23, 2016 survey. Findings: 1. A record review of American Association of Bioanalysts proficiency test (PT) results,

	revealed the laboratory failed KOH testing for 2017 Quarter 3. 2. An interview on March 22, 2018 at 9:30 AM, with the operation manager, confirmed the laboratory failed to verify the accuracy of KOH proficiency testing at least semiannually in 2017.
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 operation manager, the laboratory failed to document the evaluation of unsatisfactory PT results for potassium hydroxide (KOH) for the American Association of Bioanalysts (AAB) 2017 quarter 3 events. Findings: 1. A review of PT results from AAB 2017 quarter 3, revealed the laboratory failed to document the evaluation and corrective action for the unsatisfactory KOH test performed by the laboratory director. 2. An interview on March 22, 2018 at 9:35 AM, with the operation manager, confirmed the laboratory failed to document the evaluation and corrective action for the failed KOH test performed on the AAB 2017 quarter 3 event.
D5313	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(b) The laboratory must document the date and time it receives a specimen. This STANDARD is not met as evidenced by: Based on an observation of patient specimens, a record review, and an interview with the operation manager, the laboratory failed to document the date and time patient specimens for complete blood counts (CBCs) and other laboratory tests are submitted for testing during the day reviewed for March 22, 2018. Findings: 1. A review of two patient laboratory test requisitions for March 22, 2018 revealed the laboratory failed to indicate the date and time of patient specimens submitted to the lab for referral testing to another CLIA-certified laboratory. 2. An observation at 11:30 AM, of patient blood specimens at the Glenns Ferry Health Center, revealed the patient specimens were labeled with the patient's name and date of birth. 3. An interview on March 22, 2018 at 10:40 AM, with the operation manager, confirmed the laboratory failed to document the date and time it received patient blood specimens, as well as document on the laboratory test requisitions.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by:

	Based on a record review and an interview with the operation manager, the laboratory failed to monitor and evaluate the overall quality of complete blood count testing performed on the QBC Star analyzer, and failed to identify and correct problems of the test system. Refer to D5407, D5439, D5447, D5461, D5481, D5775, D5781, D5783, D5787, and D5789.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on an interview with the operation manager and a procedure manual review, the laboratory director failed to approve, sign, and date the manufacturer's operating manual for the QBC Star complete blood count (CBC) analyzer since the installation in January 2017 at the Glenns Ferry Health Center and April 2017 at the Desert Sage Health Center in Mountain Home. Findings: 1. A procedure review of the QBC Star CBC analyzer used by the testing personnel to perform CBC patient testing failed to be approved, signed, and dated by the laboratory director for both Health Centers since the time of installation for both analyzers. 2. An interview on March 22, 2018 at 10:20 AM, with the operation manager, confirmed the laboratory director failed to approve, sign, and date both the QBC Star CBC analyzers.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on a record review and an interview with the operation director, the laboratory failed to monitor and document the room temperature where the QBC Star analyzer was used to test patient complete blood counts (CBCs) since the last survey on March 23, 2016. This is a repeat deficiency from the March 23, 2016 survey. Findings: 1. A record review of temperature logs revealed the laboratory failed to document and monitor the room temperature where the QBC Star analyzer was used to test patient CBCs. 2. An interview on March 22, 2018, at 11:15 AM, with the operation manager, confirmed the laboratory failed to document the room temperature since the last survey.
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 a record review and an interview with the operation director, the laboratory failed to perform and document calibration verifications at least once every 6 months for the QBC Star analyzers located at Desert Sage Health Center in Mountain Home, Glenns Ferry Health Center, and Valley Health Center in Grand View, Idaho since the last survey on March 23, 2016. Findings: 1. A record review of calibration logs from Desert Sage Health Centers in Mountain Home and Glenns Ferry Health Center revealed the laboratory failed to perform and document calibration verifications at least once every 6 months for the QBC Star analyzers used to test patient CBCs since the last survey. 2. An interview on March 22, 2018, at 11:25 AM, with the operation manager, confirmed the laboratory failed to perform and document calibration verifications once every 6 months for the three QBC Star analyzers.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a quality control record review and an interview with the operation manager, the laboratory failed to test two different concentrations of quality control material for the QBC Star complete blood count (CBC) analyzer prior to reporting patient CBC results for the dates examined between January 5, 2018 through March 8, 2018. Findings: 1. A record review of Desert Sage Health Center in Mountain Home CBCs, revealed 7 out of 15 patient CBC results were reported without two levels of quality control performed during January through March 2018. 2. An interview on March 22, 2018, at 11:25 AM, with the operation manager, confirmed the laboratory testing personnel failed to perform and document two levels of quality control for the CBC analyzer prior to reporting patient CBC results.

D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a quality control record review and an interview with the operation manager, the laboratory failed to meet the quality control requirements for the QBC Star complete blood count (CBC) analyzer prior to reporting patient CBC results since the last survey on March 23, 2016. Findings: 1. A review of quality control records from Glenns Ferry Health Center from January through March 2018, revealed 5 out of 10 patient CBCs were reported when one or two levels of quality control were out of expected range. 2. An interview on March 22, 2018 at 12:25 PM, with the operation manager, confirmed the laboratory testing personnel failed to verify the two levels of quality control for the CBC analyzer were within expected range prior to reporting patient CBC results.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on a record review and an interview with the operation manager, the laboratory failed to establish a system that evaluates the three QBC Star complete blood count (CBC) analyzers located at three testing locations at least twice a year since the last survey on March 23, 2016. Findings: 1. A record review revealed the laboratory failed to establish a system to evaluate the comparison of the three QBC Star CBC analyzers located at Glenns Ferry, Mountain Home, and Grand View, Idaho since the last survey. 2. An interview on March 22, 2018, at 12:10 PM, with the operation manager, confirmed the laboratory failed to have a system in place to monitor the relationship by performing comparisons between the three CBC analyzers located at the three locations.
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 operation manager, the laboratory failed to document all corrective actions for when two levels of quality control material failed to meet the manufacturer's specifications for acceptability on the QBC Star complete blood count (CBC) analyzers from January through March 2018. Findings: 1. A review of quality control records from the Glenns Ferry Health Center, revealed the laboratory testing personnel failed to document the corrective actions taken when 10 out of 59 daily quality control material on two levels failed to meet the manufacturer's reference range at the Glenns Ferry Health Center from January through March 2018. 2. A review of quality control records from Desert Sage Health Center in Mountain Home, revealed the laboratory testing personnel failed to document the corrective actions taken when 12 out of 50 daily quality control material on two levels failed to meet the manufacturer's reference range at the Desert Sage Health Center from January through March 2018. 3. An interview on March 22, 2018, at 12:10 PM, with the operation manager, confirmed the laboratory testing personnel failed to document corrective actions when two levels of quality control for the CBC analzyer failed to meet the manufacturer's range of acceptability.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on a record review and an interview with the operation manager, the laboratory failed to evaluate patient complete blood counts (CBCs) test results when 2 levels of quality control failed to meet the criteria for acceptability at the Glenns Ferry Heath Center and the Desert Sage Health Center in Mountain Home from January through March 2018. Findings: 1. A review of quality control records and patient CBC reports from Glenns Ferry Health Center, revealed the laboratory failed to evaluate the patient CBC test results when 5 out of 10 patient CBCs where reported when the 2 levels of quality control where outside the manufacturer's reference range from January 23, 2018 through March 6, 2018. 2. An interview on March 22, 2018, at 3:00 PM, with the operation manager, confirmed the laboratory failed to evaluate patient CBC results when 2 levels of quality control for the CBCs failed to meet the manufacturer's reference range.
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 patient report reviews and an interview with the operation manager, the laboratory testing personnel failed to ensure positive identification of patient test results printed from the QBC Star complete blood count (CBC) analyzers from January through February 2018. Findings: 1. A review of the QBC Star CBC patient printouts from in Glenns Ferry Health Center, revealed 2 out of 4 patient test results failed to contain any patient information on the printouts on January 23, 2018 and February 28, 2018. 2. A review of the QBC Star CBC patient printouts from Desert Sage Health Center in Mountain Home, revealed 2 out of 2 patient test results failed to contain any patient information on the printouts on March 2, 2018 and March 18, 2018. 3. An interview on March 22, 2018, at 12:15 PM, with the operation manager, confirmed the laboratory testing personnel failed to ensure positive patient identification on the CBC patient printouts from the QBC Star analyzer.
D5789	TEST RECORDS CFR(s): 493.1283(b) Records of patient testing including, if applicable, instrument printouts, must be retained. This STANDARD is not met as evidenced by: Based on patient test results review and an interview with the operation manager, the laboratory failed to retain patient complete blood count (CBC) test result printouts from the QBC Star CBC analyzer at the Glenns Ferry Health Center and the Desert Sage Health Center in Mountain Home since the last survey on March 23, 2016. Findings: 1. A record review of patient CBC test results printed from the QBC Star CBC analyzer, revealed the laboratory failed to retain all but 8 out of 585 patient printouts at the Glenns Ferry Health Center since the last survey. 2. A record review of patient CBC test results printed from the QBC Star CBC analyzer, revealed the laboratory failed to retain all but 2 out of 1180 patient printouts at the Desert Sage Health Center in Mountain Home since the last survey. 3. An interview on March 22, 2018, at 2:50 PM, with the operation manager, confirmed the laboratory failed to retain patient CBC printouts from the QBC Star analyzers at both locations.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on a policy review and an interview with the operation manager, the laboratory failed to establish and follow written procedures for a system to monitor and correct problems in the analytic system since the last survey on March 23, 2016. Refer to

	D5439, D5447, D5461, D5481, D5775, D5781, D5783, D5787, and D5789. Findings: 1. A policy review revealed the laboratory failed to establish a quality assessment procedure to identify and correct problems in the analytic system. 2. An interview on March 22, 2018, at 4:30 PM, with the operation manager, confirmed the laboratory failed to establish a system to monitor and identify all problems related to the analytic test systems.
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 operation manager, the laboratory failed to document the units of measurement for complete blood count (CBC) analyte on the final patient test reports for the period reviewed between January 6, 2018 through March 23, 2018. Findings: 1. An electronic health record (EHR) review of seven patient CBC test reports from Desert Sage Health center in Mountain Home and Glenns Ferry Health Center, revealed the CBC results were manually entered in the patient's EHR without units of measurement for all the CBC analytes. 2. An interview on March 22, 2018, at 12:15 PM, with the operation manager, confirmed the patient CBC results that were entered into the patient's electronic health record failed to contain units of measurement for each analyte.
D5821	TEST REPORT CFR(s): 493.1291(k) When errors in the reported patient test results are detected, the laboratory must do the following: (k)(1) Promptly notify the authorized person ordering the test and, if applicable, the individual using the test results of reporting errors. (k)(2) Issue corrected reports promptly to the authorized person ordering the test and, if applicable, the individual using the test results. (k)(3) Maintain duplicates of the original report, as well as the corrected report. This STANDARD is not met as evidenced by: Based on a record review of final patient reports and an interview with the operation manager, the laboratory testing personnel failed to ensure patient complete blood count (CBC) data printed from the QBC Star analyzer at the Desert Sage Health Center in Mountain Home was accurately entered into the patient electronic health record on January 6, 2018 and February 20, 2018. Findings: 1. A patient CBC report on February 20, 2018, failed to report 2 out of 7 analytes, the white blood count and the granulocyte count. 2. A patient CBC report January 6, 2018, failed to report 2 out

	of 7 analytes, the white blood count and the granulocyte count. 3. An interview on March 22, 2018, at 3:30 PM, with the operation manager, confirmed the laboratory testing personnel failed to enter the complete blood count analytes on both patients.
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 a policy review and an interview with the operation manager, the laboratory failed to establish and follow written procedures for a system to monitor and correct problems in the post-analytic system since the last survey on March 23, 2016. Findings: 1. A policy review revealed the laboratory failed to establish a quality assessment procedure to identify and correct problems in the post-analytic system. 2. An interview on March 22, 2018, at 4:30 PM, with the operation manager, confirmed the laboratory failed to establish a system to monitor and identify all problems related to the post-analytic test systems.
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: The laboratory director failed to provide overall management and direction for the testing of complete blood counts since the last survey. This is a repeat deficiency from the survey conducted on March 23, 2016. Refer to D6004, D6020, D6021, D6025, and D6032. This is a repeat deficiency from the March 23, 2016 survey.
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b) 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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on records review, the laboratory director failed to provide oversight for the operation of the laboratory and competency of the testing personnel since the last

	survey on March 23, 2016. Findings: 1. A record review of competency for testing personnel, revealed analytic testing procedures through the post-analytic phases of patient test reporting were not accurate and failed to comply with regulations.
D6020	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 the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on a records review and an interview with the operation manager, the laboratory director failed to ensure the quality control program for the QBC Star analyzer complete blood count (CBC) test system meets the CLIA requirements since the last survey on March 23, 2016. Refer to D5447, D5481, D5781, D5783, and D5791. Findings: 1. A quality control records review for the QBC Star analyzer complete blood count (CBC) test system from both the Desert Sage Health Center in Mountain Home and the Glenns Ferry Health Center, revealed the laboratory director failed to ensure a quality control program is established to ensure that the patient test results are reported accurately. 2. An interview on March 22, 2018, at 4:30 PM, with the operation manager, confirmed the laboratory failed to meet CLIA requirements and document the quality control activities for the analytic and post-analytic phases of CBC testing.
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 records review and an interview with the operation manager, the laboratory director failed to ensure the quality assessment program for the QBC Star analyzer complete blood count (CBC) test system meets the CLIA requirements since the last survey on March 23, 2016. Refer to D5791, D5805, D5821, and D5891. Findings: 1. A policy review revealed the laboratory failed to establish a quality assessment procedure to identify and correct problems in the analytic and post-analytic systems. 2. An interview on March 22, 2018, at 4:30 PM, with the operation manager, confirmed the laboratory failed to establish and document the quality assessment activities for the analytic and post-analytic phases of CBC testing.
D6025	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(7)

	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)(7) Ensure that patient test results are reported only when the system is functioning properly. This STANDARD is not met as evidenced by: Based on quality control record review and an interview with the operation manager, the laboratory director failed to ensure that patient complete blood count results (CBCs) are reported only when the system is functioning properly during the time reviewed from January 6, 2018 through March 23, 2018. Findings: 1. A record review of 2 out of 4 patient CBCs failed to report all the CBC analytes. See D5821. 2. A record review of quality control results and patient CBC test results revealed 5 out of 10 patient CBCs were reported when 2 levels of quality control failed to meet the manufacturer's reference range from January 23, 2018 through March 6, 2018. See D5783. 3. A record review of quality control results revealed the laboratory failed to meet the quality control requirements for the QBC Star CBC analyzer prior to reporting patient CBC results. See D5481. 4. An interview on March 22, 2018, at 4:30 PM, with the operation manager, confirmed the laboratory failed to report patient CBCs only when the test system is functioning properly.
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 operation manager, the laboratory director failed to specify in writing the responsibilities and duties for each technical consultant and testing personnel engaged in the performance of all phases of testing for the QBC Star complete blood count (CBC) analyzer since the last survey on March 23, 2016. Findings: 1. A procedure manual review, revealed the laboratory failed to have in writing the responsibilities and duties for the technical consultant and testing personnel engaged in CBC testing. 2. An interview on March 22, 2018, at 9:40 AM, with the operation manager, confirmed the laboratory director did not specify in writing the job duties of each person involved in laboratory testing.
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 a record review and an interview with the operation manager, the laboratory failed to provide documentation to qualify the off-site technical consultant. The technical consultant failed to perform the duties for technical consultant oversight. Refer to D6034, D6044, D6046, D6049, and D6053. Findings: 1. A record review of personnel documents revealed the laboratory failed to ensure the technical consultant was qualified prior to providing technical consultation for the laboratory in the specialty of hematology since the last survey. See D6034. 2. A personnel record review, revealed the laboratory failed to have a qualified individual perform competency assessments for the 10 testing personnel listed on the CMS-209 Personnel Report form in 2017. See D6036. 3. A record review of personnel documents revealed 5 out of 10 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. See D6053. 4. An interview on March 22, 2018 at 9:45 AM, with the operation manager, confirmed the laboratory failed to qualify the technical consultant and assess employee competency during 2017.
D6034	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 The laboratory must employ one or more individuals who are qualified by education and either training or experience to provide technical consultation for each of the specialties and subspecialties of service in which the laboratory performs moderate complexity tests or procedures. The director of a laboratory performing moderate complexity testing may function as the technical consultant provided he or she meets the qualifications specified in this section. This STANDARD is not met as evidenced by: Based on a record review of personnel documents and an interview with the operation manager, the laboratory failed to ensure the technical consultant was qualified prior to providing technical consultation for the laboratory in the specialty of hematology since the last survey on March 23, 2016. Findings: 1. A review of personnel education documents revealed that the laboratory failed to qualify the technical consultant listed on the CMS-209 Personnel Report form prior to providing technical consultation to laboratory. 2. An interview on March 22, 2018 at 9:40 AM, with the operation manager, confirmed the laboratory failed to qualify the technical consultant who provides technical consultation for the laboratory.
D6044	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(6) (b) The technical consultant is responsible for-- (b)(6) Ensuring that patient test results are not reported until all corrective actions have been taken and the test system is functioning properly; This STANDARD is not met as evidenced by:

	Based on quality control records and an interview with the operation manager, the technical consultant failed to ensure patient test results were not reported until corrective actions have been taken since the last survey on March 23, 2016. Findings: 1. The laboratory failed to establish and follow written procedures for a system to monitor and correct problems in the analytic and post-analytics system since the last survey. 2. An interview on March 22, 2018 at 4:30 PM, with the operation manager, confirmed the laboratory failed to have systems in place to ensure patient results are not reported until the QBC Star complete blood count system is functioning properly.
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 operation manager, the laboratory failed to have a qualified individual perform competency assessments for the 10 testing personnel listed on the CMS-209 Personnel Report form performing complete blood counts in 2017. Findings: 1. A review of personnel records revealed the laboratory failed to have a qualified individual perform competency assessments on the 10 personnel listed on the CMS-209 Personnel Report form in 2017. 2. An interview on March 22, 2018 at 9:30 AM, with the operation manager, confirmed the laboratory failed to have a qualified individual perform competency assessments on the testing personnel.
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 operation manager, the laboratory failed to establish and follow a written procedure for assessing employee competency at least semiannually during the first year of patient testing on the QBC Star analyzer used to test complete blood counts since the last survey on March 23, 2016. Findings: 1. A record review of personnel documents revealed 5 out of 10 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 March 22, 2018 at 9:30 AM, with the operation manager, confirmed the laboratory failed to perform competency at least semiannually on 5 testing personnel.