Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	13D2032859	09/19/2018
Name of Provider or Supplier	**Street Address, City, State**	
Rehabilitative Health Services Medical Clinic	1675 Curlew Dr, 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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on a record review and an interview with the laboratory lead, revealed the laboratory failed to enroll in proficiency testing (PT) for the specialty of hematology for complete blood counts (CBCs) since the start of patient testing in October 2016. Findings: 1. A review of documents revealed the laboratory failed to enroll in PT for the specialty of hematology CBC analytes since the start of patient testing in 2016. 2. An interview on September 19, 2018 at 3:30 PM, with the laboratory lead and laboratory director, confirmed the laboratory failed to enroll in PT for CBC analytes.
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 and director, the laboratory failed to retain external quality control data from the Sysmex pocH-100 since the start of patient testing in October 2016. Findings: 1. A review of quality control records revealed the laboratory failed to retain all three levels of quality control data from the Sysmex pocH-100 complete blood count analyzer since October 2016. 2. An interview on September 19, 2018 at 3:45 PM, with the laboratory lead and laboratory director, confirmed the laboratory failed to retain all quality control data printouts from the CBC analyzer.
D5200	GENERAL LABORATORY SYSTEMS CFR(s): 493.1230 Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, 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 general laboratory systems and correct identified problems specified in 493.1239 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 laboratory lead and laboratory director, the laboratory failed to monitor and evaluate the overall quality of the general laboratory system for the specialty of hematology since October 2016. Refer to D5203, D5209, and D5217.
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: Based on a record review and an interview with the laboratory lead and laboratory director, the laboratory failed to establish and write procedures and policies that ensure positive patient identification and integrity of a patient's blood specimen since the start of patient testing in October 2016. Findings: 1. A review of records revealed the laboratory failed to establish and write policies and procedures to ensure positive patient identification from the time of collection to the reporting of test results. 2. An interview on September 19, 2018 at 4:00 PM, with the laboratory lead and laboratory director, confirmed the laboratory failed to establish procedures that ensure positive patient identification from the time of collection to the final reporting of patient test results.
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 and an interview with the laboratory lead, the laboratory failed to establish and write procedures and policies to assess testing personnel competency in the specialty of hematology performing complete blood counts (CBCs) and microscopic fungal examinations using potassium hydroxide (KOH) since the start of patient testing in October 2016. Findings: 1. A review of personnel records revealed the laboratory failed to establish and write policies and procedures to evaluate the competency for 6 out of 6 testing personnel listed on the CMS-209 Personnel Report form performing CBCs and KOH examinations. 2. An interview on September 19, 2018 at 3:10 PM, with the laboratory lead, confirmed the laboratory failed to write and follow procedures to evaluate the competency of testing personnel.
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 laboratory lead, the laboratory failed to verify the accuracy of microscopic fungal examinations using potassium hydroxide (KOH) at least twice a year since the start of patient testing in October 2016. Findings: 1. A review of records revealed the laboratory failed to verify the accuracy of microscopic fungal examinations using KOH at least twice a year since October 2016. 2. An interview on September 19, 2018 at 4:20 PM, with the laboratory lead, confirmed the laboratory failed to verify the accuracy at least twice a year the microscopic examination of fungal elements from the skin.
D5301	TEST REQUEST CFR(s): 493.1241(a) The laboratory must have a written or electronic request for patient testing from an authorized person. This STANDARD is not met as evidenced by: Based on a record review and an interview with the laboratory lead, the laboratory failed to have a written request or electronic request for complete blood counts (CBCs) ordered and performed on 4 patient specimens on September 4, 2018. Findings: 1. A review of patient reports revealed the laboratory failed to have a written or electronic request for 4 patient CBC tests performed on patient specimens. 2. An interview on September 19, 2018 at 4:20 PM, with the laboratory lead, confirmed the laboratory failed to receive a written test request for 4 patient CBCs performed on September 4, 2018.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3)

	Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on a record review and an interview with the laboratory lead and laboratory director, the laboratory failed to establish and write policies and procedures for patient preparation, specimen collection and labelling, specimen storage and transportation, specimen processing, acceptability and rejection since the start of patient testing in October 2016. Findings: 1. A review of records in the laboratory revealed the laboratory failed to establish and write procedures and policies to provide guidance to testing personnel in the preanalytic processing steps for a patient's specimen. 2. An interview on September 19, 2018 at 4:45 PM, with the laboratory lead and laboratory director, confirmed the laboratory failed to establish and write procedures for the preanalytic specimen processing steps.
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 record reviews, the laboratory failed to monitor, evaluate, and correct problems in the analytic system since the start of patient testing in October 2016. Refer to D5401, D5413, D5417, D5421, D5433, and D5437.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on a record review and an interview with the laboratory lead and laboratory director, the laboratory failed to write policies and procedures for all tests performed in the laboratory since October 2016. Findings: 1. A review of records revealed the laboratory failed to write procedures for complete blood count testing and microscopic examinations of fungal skin specimens since October 2016. 2. An interview on September 19, 2018 at 4:45 PM, with the laboratory lead and laboratory director, confirmed the laboratory failed to establish and write procedures for tests performed in the laboratory.

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 laboratory lead, the laboratory failed to document the room temperature of the laboratory and the refrigerator where quality control material for complete blood counts (CBCs) are stored since the start of patient testing in October 2016. Findings: 1. A review of the records for the laboratory revealed the laboratory failed to record the temperature of the laboratory room and refrigerator where quality controls for the Sysmex pocH-100 complete blood count (CBC) are stored and tested since October 2016. 2. An interview on September 19, 2018 at 3:45 PM, with the laboratory lead, confirmed the laboratory staff failed to record the temperature of the laboratory and the refrigerator where CBC quality controls are stored and tested.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on an observation and an interview with the laboratory lead, the laboratory failed to use the Sysmex pocH-100 complete blood count (CBC) external quality control materials within the timeframe established by the manufacturer since October 2016. Findings: 1. An observation of the laboratory refrigerator on September 19, 2018 revealed the laboratory stored Eightcheck-3WP tri-level quality control materials that were used past their expiration date when opened for testing. 2. An interview on September 19, 2018 at 3:35 PM, with the laboratory lead, confirmed the external quality control material for CBC failed to be used within the expiration date specified by the manufacturer and that the expired controls were being used when testing and reporting patient CBC specimens.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for

	the laboratory's patient population. This STANDARD is not met as evidenced by: Based on a record review and an interview with the laboratory lead, the laboratory failed to perform and document the accuracy and precision of the Sysmex pocH-100 complete blood count (CBC) hematology analyzer prior to reporting patients results on October 16, 2016. Findings: 1. A record review of the installation verification activities for the Sysmex pocH-100 CBC analyzer revealed the laboratory failed to perform accuracy and precision studies before reporting patient results. 2. An interview on September 19, 2018 at 4:15 PM, with the laboratory lead, confirmed the laboratory failed to verify the accuracy and precision of the CBC analyzer prior to reporting patient results since October 16, 2016.
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 lead, the laboratory failed to establish and document unscheduled maintenance or preventative maintenance activities for the Sysmex pocH-100 complete blood count (CBC) hematology analyzer since the start of patient testing in October 2016. Findings: 1. A record review of the laboratory procedures revealed the laboratory failed to establish a corrective action procedure for documenting unscheduled or preventative maintenance activities on the analyzer in the lab since October 2016. 2. An interview on September 19, 2018 at 3:55 PM, with the laboratory lead, confirmed the laboratory failed to establish and document unscheduled maintenance activities for the CBC 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 lead, the laboratory failed to perform and document calibration procedures at least once every 6 months or as required by the manufacturer for the Sysmex pocH-100 complete blood count (CBC) hematology analyzer since the start of patient testing in October 2016. Findings: 1. A record review of calibration reports for the Sysmex CBC analyzer revealed the laboratory failed to perform and document calibration activities at least once every 6 months or as recommended by the manufacturer since the initial calibration in October of 2016. 2. An interview on September 19, 2018 at 13:45 PM, with the laboratory lead, confirmed the laboratory failed to perform and document calibration procedure activities for the Sysmex analyzer.
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 document the units of measurement for complete blood count (CBC) analytes on the final patient test reports since the start of patient testing in October 2016. Findings: 1. A review of patient CBC test reports from August 31, 2018 through September 6, 2018 revealed the units of measurements for CBC analytes failed to be indicated on the patient's final report. 2. An interview on September 19, 2018 at 2:35 PM, with the laboratory lead, confirmed the units of measurement for each CBC analyte was not indicated on the patient CBC test report.
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 start of patient testing in October 2016. Refer to D6004, D6013, D6015, D6020, D6021, D6030, and D6031.
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 meet the responsibilities for the overall operation of the laboratory to assure compliance with CLIA regulations since October 2016. Findings: 1. A review of records from the pre-analytic, analytic, post-analytic, and general laboratory systems revealed the laboratory director failed to meet the regulations for all phases of patient testing and reporting since the start of patient testing.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) 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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on a record review and an interview with the laboratory director, the laboratory director failed to ensure all verification procedures for the Sysmex pocHi-100 complete blood count (CBC) hematology analyzer met the performance specifications for the laboratory since the time of installation in October 2016. Findings: 1. A record review of the Sysmex accuracy and precision data revealed the laboratory director failed to verify that the hematology analyzer met all verification procedures and met the laboratory's performance criteria since the installation in October 2016. 2. An interview on September 19, 2018 at 4:35 PM, with the laboratory director, confirmed the laboratory director failed to ensure the hematology analyzer met all verification activities prior to reporting patient test results.
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) 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)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on a record review and an interview with the laboratory director, the laboratory

	director failed to ensure the laboratory was enrolled in proficiency testing (PT) for the specialty of hematology testing complete blood count (CBC) since the start of patient testing in October 2016. Findings: 1. A record review of PT for the CBC analytes revealed the laboratory director failed to enroll in a CMS-approved PT provider since October 2016. 2. An interview on September 19, 2018 at 4:35 PM, with the laboratory director, confirmed the laboratory director failed to enroll in PT in the specialty of hematology.
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 record review and an interview with the laboratory lead, the laboratory director failed to ensure the quality control program for the Sysmex pocH-100 complete blood count (CBC) hematology analyzer meets the CLIA requirements since October 2016. Findings: 1. A quality control records review for the Sysmex hematology analyzer revealed the laboratory director failed to ensure a quality control program was established to ensure that patient test results are reported accurately. 2. An interview on September 19, 2018 at 4:35 PM, with the laboratory director, confirmed the laboratory director failed to meet CLIA requirements for the quality control activities in 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 records review and an interview with the laboratory director, the laboratory director failed to ensure the quality assessment programs for the Sysmex pocH-100 complete blood count (CBC) hematology analyzer and microscopic fungal examinations are established and meets the CLIA requirements since the start of patient testing in October 2016. Findings: 1. A record review revealed the laboratory director failed to establish and write polices and procedures for a system to monitor, assess, and correct problems in the preanalytic, general laboratory system, analytic, and post-analytic processes in the laboratory. 2. An interview on September 19, 2018 at 4:35 PM, with the laboratory director, confirmed the laboratory director failed to

	establish and write policies and procedures for a system to monitor all quality assessments activities for the laboratory's test performance in CBC and fungal examinations.
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 record review and an interview with the laboratory lead, the laboratory director failed to ensure that policies and procedures were established for monitoring the competency of testing personnel performing complete blood counts (CBCs) and microscopic fungal examinations since the start of patient testing in October 2016. Findings: 1. A record review revealed the laboratory failed to establish and write policies or procedures to monitor the competency of 6 out of 6 testing personnel listed on the CMS-209 Personnel Report form performing CBCs and microscopic fungal examinations. 2. A review of personnel competency documents revealed competency assessments for the 6 testing personnel was not performed. 3. An interview on September 19, 2018 at 4:35 PM, with the laboratory director, confirmed the laboratory director failed to establish and write policies and procedures to monitor testing personnel performing all phases of testing in the laboratory.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) 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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; 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 ensure a procedure manual was approved for all phases of testing for complete blood counts (CBCs) and microscopic fungal examinations since the start of testing in October 2016. Findings: 1. A record review revealed the laboratory director failed to ensure a procedure manual was approved and available to all testing personnel in the laboratory. 2. An interview on September 19, 2018 at 4:35 PM, with the laboratory lead, confirmed the laboratory director failed to approve and make available a procedure manual for all phases of testing in the laboratory.

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 the laboratory director who is listed as the technical consultant, failed to meet the qualifications to be a technical consultant and provide technical oversight for the laboratory in the specialty of hematology since October 2016. Refer to D6035, D6036, and D6046.
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 of personnel documents and an interview with the laboratory director, the laboratory director failed to qualify as the technical consultant

	to provide technical consultation for the laboratory in the specialty of hematology since October 2016. Findings: 1. A review of personnel documents revealed the laboratory director failed to qualify for the position of technical consultant and failed to provide technical consultation to laboratory. 2. An interview on September 19, 2018 at 4:45 PM, with the laboratory director, confirmed the laboratory director failed to qualify for the position as technical consultant.
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 lead, the laboratory director who is listed as the technical consultant, failed to provide technical and scientific oversight for the testing of complete blood counts and microscopic fungal examinations since October 2016. Findings: 1. A review of quality control documents, calibration documents, and general laboratory systems revealed the technical consultant who is listed as the laboratory director, failed to monitor quality control data, calibration activity, and general laboratory function. 2. An interview on September 19, 2018 at 4:45 PM, with the laboratory lead, confirmed the laboratory director failed to provide the technical oversight for the laboratory.
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 and an interview with the laboratory lead, the laboratory director who is listed as the technical consultant, failed to qualify to perform and failed to evaluate the competency of all testing personnel performing complete blood counts (CBC) and microscopic fungal examinations using potassium hydroxide (KOH) since October 2016. Findings: 1. A review of personnel documents revealed the technical consultant failed to evaluate the competency of 6 out of 6 testing personnel listed on the CSM-209 Personnel Report form performing CBC and KOH examinations. 2. An interview on September 19, 2018 at 4:45 PM, with the laboratory lead, confirmed the technical consultant failed to assess and document competency for the testing personnel.