Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D0398011	07/19/2023
Name of Provider or Supplier	**Street Address, City, State**	
La Clinica De Los Campesinos, Inc	400 S Townline Rd, Wautoma, WI	

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 surveyor review of the federal Certification and Survey Provider Enhanced Reports (CASPER) and laboratory records, and interview with testing personnel, the laboratory performed patient testing with the Horiba ABX Micros 60 hematology analyzer (Micros 60) starting on November 9, 2022, and did not enroll in an approved PT (proficiency testing) program for six of six regulated analytes in hematology. Findings include: 1. Review of CASPER report 155 'Individual Laboratory Profile' for La Clinica de los Campesinos, Inc., CLIA number 52D0398011, showed no results for the hematology specialty since the third event of 2020, including the following regulated analytes: cell identification or white blood cell (WBC) differential, red blood cell count, hematocrit, hemoglobin, WBC count, and platelets. 2. Review of the 'Multiple Patient Result Report' from the Family Health La Clinica Micros 60 showed testing personnel performed patient testing from November 2022 through July 2023. 3. Review of laboratory records showed no evidence the laboratory performed proficiency testing in 2022 or 2023. 4. Interview with testing personnel (staff C and D) on July 19, 2023, at 10:55 AM confirmed the laboratory did not enroll in PT for

	the six regulated hematology analytes performed on the Micros 60 and confirmed the laboratory performed and reported patient hematology test results including the six regulated analytes since November 9, 2022.
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 surveyor review of laboratory records and interview with testing personnel, the laboratory retained zero out of approximately three hundred complete blood count (CBC) patient test reports printed by the Horiba ABX Micros 60 hematology analyzer (Micros 60) since testing started in November 2022. Findings include: 1. Review of laboratory records showed no evidence staff retained the Micros 60 patient test report printed by the analyzer at the time of testing. 2. Interview with testing personnel (staff C) on July 19, 2023, at 1:30 PM revealed testing personnel discarded the results printed by the Micros 60 after testing personnel manually entered the results into the patient electronic medical record. Further interview revealed personnel analyzed more than three hundred patient samples with the Micros 60 since November 9, 2022, when personnel started patient testing.
D5024	HEMATOLOGY CFR(s): 493.1215 If the laboratory provides services in the specialty of Hematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1269, and 493. 1281 through 493.1299. This CONDITION is not met as evidenced by: Based on surveyor review of laboratory procedures and records and interview with the director of medical services and testing personnel, the laboratory did not meet the requirements specified in 493.1230 through 493.1256 and 493.1281 through 493.1299. Findings include: 1. The laboratory did not develop procedures or ensure consistent positive identification of a patient's results throughout the testing and reporting process. See D5203. 2. The laboratory director did not approve, sign, and date laboratory procedures. See D5407. 3. The laboratory did not verify the manufacturer's reference intervals (normal ranges) for the hematology test system. See D5421. 4. The laboratory did not have a method to ensure personnel entered test results accurately into the medical record. See D5801. 5. The laboratory did not document the reporting of critical values to providers. See D5813.
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 surveyor review of laboratory procedures, instrument reports, and patient medical records, and interview with the director of medical services, the laboratory did not develop procedures to ensure consistent sample and result identification. Additionally, laboratory testing personnel did not ensure positive identification of patients' hematology results through testing and reporting for two of five reviewed patient complete blood count (CBC) test results. Findings include: 1. Review of laboratory procedures showed no approved procedure for the use of the Horiba ABX Micros 60 hematology analyzer (Micros 60) that described sample identification through the testing process. 2. Review of the Micros 60 report 'Multiple Patient Test Result Report' showed testing personnel (identified as "User" in the report) performed testing on samples from patients two and three on July 13, 2023. The Micros 60 analyzer report showed testing personnel tested a sample at 11:30 AM and identified the results in the Micros 60 with patient two's name. Personnel tested a different sample at 4:51 PM and identified the results in the Micros 60 analyzer with patient three's name. 3. Review of patient electronic medical records (EMR) and comparison with the 'Multiple Patient Result Report' from the Micros 60 analyzer revealed the following: The EMR for patient three showed the provider ordered a CBC at 11:08 AM. The 'Multiple Patient Result Report' showed a sample (identified as from patient two on the analyzer report) was tested at 11:30 AM. The CBC results in the EMR for patient three match the results from the 'Multiple Patient Result Report' tested at 11:30 AM. The EMR for patient two showed the provider ordered a CBC at 4:38 PM. The 'Multiple Patient Result Report' showed a sample (identified as from patient three on the analyzer report) was tested at 4:51 PM. The CBC results in the EMR for patient two match the results from the 'Multiple Patient Result Report' tested at 4:51 PM. 4. During an interview with the director of medical services (staff B) on July 19, 2023, at 2:00 PM, staff B stated the correct results were entered in the EMR for patients two and three and confirmed testing personnel did not correctly enter the patient identifying information in the analyzer. Further interview confirmed the laboratory had not established policies and procedures that ensured consistent sample and result identification throughout the testing process and reporting of results.
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 surveyor review of the laboratory procedure manuals and interview with testing personnel, the laboratory director had approved, signed, and dated only one of seven reviewed procedures that applied to non-waived testing. Findings include: 1. Review of the laboratory procedure manuals showed the laboratory director approved, signed, and dated the 'Laboratory Standing Orders' procedure on March 31, 2022. The manual showed no evidence the director had approved, signed, and dated the other procedures in the manuals. 2. Interview with testing personnel (Staff C and D) on July 19, 2023, at 12:15 PM confirmed the laboratory director did not document approval of the laboratory procedures. This is a repeat deficiency previously cited on December 27, 2018.

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 surveyor review of laboratory procedures, manufacturer's instructions for the Afinion hemoglobin A1c test cartridge (HbA1cDx), and records, observation in the laboratory, and interview with testing personnel, the laboratory did not define acceptable room temperature requirements for one of one laboratory room in the clinic. Findings include: 1. Review of laboratory procedures showed no defined acceptable temperature range for equipment or supplies. 2. Observation in the laboratory on July 19, 2023, at 9:30 AM showed Afinion HbA1c Dx test cartridges stored at room temperature. 3. Review of the manufacturer's instructions for the Afinion HbA1c Dx Test Cartridges showed the manufacturer's acceptable temperature range for cartridges stored at room temperature was 59 - 77 F (degrees Fahrenheit). 4. Review of verification records for the Afinion 2 HbA1c test system showed the laboratory started verification on April 17, 2023. 5. Review of laboratory records showed personnel used a log in 2023 to record temperatures in the laboratory. The log does not show the laboratory's acceptable range for storage or operation of equipment or supplies. Review of the log showed personnel recorded temperatures at or above 78 F on two of seventy-six days when they recorded temperatures from April 17 through July 19, 2023. 6. Interview with testing personnel (staff C and D) on July 19, 2023, at 12:30 PM confirmed the laboratory had not defined an acceptable temperature range consistent with the manufacturer's instructions for storage of equipment and supplies in the laboratory.
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 surveyor review of laboratory records and interview with testing personnel, the laboratory did not verify the manufacturers' reference intervals (normal values) were appropriate for the laboratory's patient population for two of two non-waived test systems. Findings include: 1. Review of the 'Afinion Implementation Forms' for the two Afinion analyzers in the laboratory and the records from the Horiba ABX Micros 60 hematology analyzer (Micros 60) showed no indication the laboratory

	evaluated the manufacturer's reference intervals and included no reference identifying what normal ranges the laboratory used to evaluate results from the two test systems. 2. Interview with testing personnel (staff C and D) on July 19, 2023, at 12:00 PM confirmed the laboratory did not verify the manufacturer's reference intervals for the Afinion 2 analyzers or the Micros 60.
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Based on surveyor review of patient test reports and laboratory records and interview with testing personnel, the laboratory did not have a system in place to verify testing personnel accurately entered test results into the Electronic Health Record (EHR) from two of two non-waived test systems. Findings include: 1. Review of patient test reports from the Afinion 2 analyzers and the Horiba ABX Micros 60 hematology analyzer (Micros 60) showed no evidence the laboratory verified the accuracy of results testing personnel had manually transcribed into the EHR. 2. Review of laboratory quality records showed no evidence the laboratory verified accuracy of manually entered results. 3. Interview with testing personnel (staff C and D) on July 19, 2023, at 2:30 PM confirmed the laboratory does not have a system in place to verify testing personnel accurately transcribed the results from the Afinion 2 analyzers or the Micros 60 into the EHR.
D5813	TEST REPORT CFR(s): 493.1291(g) The laboratory must immediately alert the individual or entity requesting the test and, if applicable, the individual responsible for using the test results when any test result indicates an imminently life-threatening condition, or panic or alert values. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory procedures and records and patient test reports in the electronic medical record, and interview with the director of medical services, the laboratory did not alert the provider or document provider notification of two of two reviewed critical hemoglobin values as required by the laboratory's procedures. Findings include: 1. Review of laboratory procedures showed the 'Critical Test / Critical Result Reporting' procedure defined hemoglobin values less than 8 as a critical result. The procedure stated, "Results from critical tests and critical results must be called after verification in the laboratory. Results are called to authorized staff or the responsible licensed caregiver." The procedure also states, "The read back process should be documented in the patient's medical record." 2. Review of the 'Multiple Patient Result Report' from the Horiba ABX Micros 60 hematology analyzer

	showed patient test results through July 18, 2023 including two patient test reports (patient 1 and 2) with hemoglobin values less than 8 g/dL (grams / deciliter). Patient / test date / hemoglobin result (g/dL) Patient 1 / February 23, 2023 / 6.9 Patient 2 / July 13, 2023 / 5.6 The report did not show that testing personnel verified either critical hemoglobin result. The report did not include a repeat test for either patient. 3. Review of patient's results in the electronic medical record showed the report flagged the critical hemoglobin results as 'abnormal' but did not show the results were critical. No documentation is present showing the testing personnel alerted the provider to the critical result. 4. Interview with the director of medical services (staff B) on July 19, 2023, at 12:45 PM revealed testing personnel did not call critical value results to the providers and confirmed testing personnel did not follow the procedure for critical value reporting.
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 surveyor review of laboratory procedures, records, and submitted survey documents and interview with testing personnel and the director of medical services, the director did not provide overall management and direction in accordance with 493. 1407 of this subpart. Findings include: 1. The director did not ensure the performance specifications of the Afinion 2 analyzers and the Horiba ABX Micros 60 hematology analyzer (Micros 60) met the performance specifications defined by the manufacturer. See D6013. 2. The director did not ensure the laboratory enrolled in an approved proficiency testing program for the regulated hematology analytes reported from the Micros 60. See D 6015. 3. The director did not establish a quality control program that met regulatory requirements for testing on the Afinion 2 analyzers. The director also did not ensure monitoring of quality control testing on the hematology analyzer was performed to ensure ongoing quality. See D6020. 4. The director did not establish and implement a quality assessment program to ensure ongoing quality of laboratory services. See D6021. 5. The director did not ensure testing personnel had the required credentials and training or experience to perform non-waived testing. See D6029. 6. The director did not ensure approved procedures were available for the two non-waived test systems in the laboratory. See D6031. 7. The director did not specify in writing the responsibilities and duties of each testing personnel. See D6032.
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: Item 1: Based on surveyor review of verification records from April 2023 for Hemoglobin A1c testing on the Afinion 2 analyzer and interview with testing personnel, the director did not evaluate the results of the verification procedures to determine whether the accuracy, precision, and reportable range of the test systems met the manufacturer's specifications or were adequate to provide quality results for two of two analyzers. Findings include: 1. Review of the verification records for the two Afinion 2 analyzers used by the laboratory to perform Hemoglobin A1c testing showed no evidence of evaluation of the results. The records also did not show the laboratory director had reviewed and accepted the results or approved the test system for use in patient testing. 2. Interview with testing personnel (staff C) on July 19, 2023 at 11:45 AM confirmed the laboratory director had not approved, signed, or dated the verification records for the Afinion 2 Hemoglobin A1c test system to show evaluation of the accuracy, precision, and other performance characteristics of the test system and to document the determination that the systems were acceptable for use in patient testing. Item 2: Based on surveyor review of laboratory records and interview with testing personnel, the laboratory director did not evaluate the results of testing performed to verify the procedures were adequate to ensure quality hematology results from the Horiba ABX Micros 60 hematology analyzer (Micros 60). Findings include: 1. Review of laboratory records for the Micros 60 showed the analyzer was calibrated on November 7, 2022. No other verification report or records showing the laboratory verified the performance of the analyzer were available. 2. Interview with testing personnel (staff C) on July 19, 2023, at 12:15 PM revealed the manufacturer installed the Micros 60 in the laboratory in May 2022 but the laboratory did not use the analyzer for patient testing until November 9, 2022. Further interview revealed the laboratory had not demonstrated the analyzer could obtain performance specifications comparable to those established by the manufacturer for accuracy, precision, and reportable ranges, and that the director had not evaluated the performance of the analyzer to ensure quality.
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 surveyor review of laboratory records and interview with testing personnel, the laboratory director did not ensure the laboratory enrolled in a proficiency testing (PT) program for nine of nine months since starting regulated hematology testing in November 2022. Findings include: 1. Review of laboratory records showed no evidence the laboratory enrolled in an approved PT program in 2022 or 2023. See D2000. 2. Interview with testing personnel (staff C and D) on July 19, 2023, at 10:55 AM confirmed the laboratory had not enrolled in an approved PT program for hematology in 2022 or 2023.
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: Item one: Based on surveyor review of quality control (QC) and patient test records and interview with testing personnel, the laboratory director did not ensure maintenance of the quality control program for Hemoglobin A1c (HbA1c) testing. Findings include: 1. Review of the 'Afinion HbA1c External Quality Control Log' from May 12 through June 22, 2023, for each of the two Afinion 2 analyzers showed the laboratory used control lot numbers 92952143 (level one) and 92952144 (level two) with open expiration dates of June 17, 2023. The logs showed Staff C tested two levels of external controls on May 12, May 23, June 15, and June 22, 2023, and showed Staff C used expired controls on June 22, 2023. Further review of the QC logs showed staff C performed all QC testing from May 12 through June 22, 2023 using lot number 10220386 of HbA1c test cartridges. The logs included an area to document review and the date of review. Testing personnel (Staff C) initialed and dated the logs on May 12, 2023. The log showed no evidence of review by the laboratory director who is also the technical consultant. 2. Review of patient test records on analyzer printouts showed the laboratory performed patient testing with lot number 10220386 on June 14, 2023, and lot number 10221676 on and after June 16, 2023. Review of quality control records on analyzer printouts showed testing personnel used cartridge lot number 10221676 for control testing on June 15 and June 22, 2023. 3. Interview with testing personnel (staff C) on July 19, 2023, at 3:00 PM confirmed they (staff C) had not completed the log accurately and confirmed the laboratory director had not evaluated QC records from the Afinion 2 analyzers. Item two: Based on surveyor review of quality control records for the Horiba ABX Micros 60 hematology analyzer (Micros 60), observation of records retained in the analyzer, and interview with testing personnel, the laboratory director did not ensure staff maintained the quality control program to assure quality of results. Findings include: 1. Review of quality control records from the Micros 60 showed testing personnel documented corrective actions taken on the printout of daily quality control results from the analyzer. The records showed no evidence of review by the laboratory director who is also the technical consultant. 2. Observation of the quality control records in the Micros 60 on July 19, 2023, at 12:00 PM showed Levy-Jennings charts of control results. No evidence of review was available. 3. Interview with testing personnel (staff C) on July 19, 2023 at 12:15 PM revealed the laboratory director had not reviewed quality control results for the Micros 60 to ensure appropriate corrective actions were taken when controls were not acceptable and to ensure control results over time were not showing signs of reduced quality, including shifts and trends in the results.
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 surveyor review of procedures and interview with the director of medical services, the laboratory director has not ensured the establishment and maintenance of a quality assessment program to ensure the ongoing quality of laboratory services. Findings include: 1. Review of laboratory procedures showed no evidence the laboratory had developed a quality assessment program that encompassed the full laboratory operation. No quality assessment plan was evident in the procedure manuals. 2. Interview with the director of medical services (Staff B) on July 19, 2023, at 3:05 PM confirmed the laboratory had not developed a quality assessment program to ensure the ongoing quality of laboratory services.
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 surveyor review of survey documents and personnel records and interview with the director of medical services, the laboratory director did not ensure testing personnel had the appropriate education and experience to perform non-waived testing. The laboratory did not have acceptable credentials for six of seven testing personnel. See D6065.
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 surveyor review of the laboratory procedure manuals and interview with testing personnel, the laboratory director did not ensure approved procedures were available for operation of the Horiba ABX Micros 60 hematology analyzer (Micros 60) or the Afinion 2 Hemoglobin A1c test; two of two non-waived test systems did not have approved procedures available. Findings include: 1. Review of laboratory procedure manuals showed no approved procedures for operation of the Micros 60.

	Further review revealed no procedures for the hemoglobin A1c test performed with the Afinion 2 analyzer. 2. Interview with testing personnel on July 19, 2023, at 12:15 PM revealed the laboratory had manufacturer's manuals for the Micros 60 and the Afinion 2 analyzers, confirmed neither was specific for the testing procedures as performed in the laboratory, and confirmed the director had approved neither manual for use as a laboratory procedure.
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 surveyor review of laboratory procedures and competence evaluation records and interview with testing personnel, the laboratory director had not specified in writing the responsibilities and duties of seven of seven testing persons to show which tests and procedures each individual was authorized to perform, whether supervision was required, and whether consultant or director review was required prior to reporting patient test results. Findings include: 1. Review of laboratory records showed no consolidated record documenting the responsibilities and duties of each testing person. 2. Review of two versions of Competence Assessment forms, 'Medical Assistant / Lab Competency Checklist' and 'Medical Assistant Lab Skills', showed staff C or G evaluated testing personnel and marked each test as "Pass" or "Fail". Testing personnel (Staff C or G) marked the forms "Pass" for Complete Blood Count (CBC) testing for six testing personnel (staff C, D, E, F, G, and I). Additionally, staff C marked one form "Pass" for CBC testing that did not include an employee's name and a second form that the testing person had signed but was unreadable. A third incomplete form that did not include the testing person's name was included with the other competence forms. The forms showed no evidence the laboratory director (who is also the technical consultant) reviewed the forms or determined whether each staff member was authorized to perform the evaluated tests. 3. Interview with testing personnel (staff C) at 2:30 PM revealed they (staff C) had approved staff C, D, and E to perform testing on the Horiba ABX Micros 60 hematology analyzer. Further interview confirmed competency forms showed additional staff could also perform testing on the analyzer and confirmed the director had not specified in writing the responsibilities of each testing person.
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 surveyor review of submitted survey forms, personnel and laboratory records, and interviews with the director of medical services and testing personnel, the technical consultant did not meet the qualification requirements of 493.1411 and did not provide technical oversight in accordance with 493.1413 of this subpart. Findings include: 1. The technical consultant did not have the required training or experience in non-waived testing to meet the qualification requirements. See D6035. 2. The technical consultant did not establish a quality control program that met the regulatory requirements for hemoglobin A1c testing on the Afinion 2 analyzers. See D6042. 3. The technical consultant did not evaluate testing personnel competence. See 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 surveyor review of the submitted CMS209 form 'Laboratory Personnel Report' and personnel records, and email correspondence with the director of medical services, one of one identified technical consultant did not meet the laboratory

	training or experience requirement to qualify as a technical consultant. Findings include: 1. Review of the CMS209 form showed the laboratory director (staff A) identified as the technical consultant. The form did not identify any other technical consultant. 2. Review of personnel records showed no evidence Staff A received training or had experience performing non-waived testing. 3. Email correspondence with the director of medical services (staff B) on July 27, 2023, at 8:33 AM confirmed staff A "only has waived lab experience".
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: Based on surveyor review of procedures and laboratory records and interview with testing personnel, the technical consultant did not establish a quality control program that met the regulatory requirements for testing Hemoglobin A1c with two of two Afinion 2 analyzers using the Afinion HbA1c Dx cartridges. The laboratory had not developed an Individualized Quality Control Plan (IQCP) and had not tested two levels of external controls each day of testing since personnel started testing in May 2023. Findings include: 1. Review of procedures showed no evidence of an IQCP for hemoglobin A1c testing on the Afinion 2 analyzers. 2. Review of laboratory quality control records for the Afinion HbA1c Dx cartridges from 2023 showed the laboratory tested two levels of external controls with each new lot or shipment of cartridges and at least every 30 days. 3. Interview with testing personnel (staff C) on July 19, 2023, at 12:00 PM confirmed the laboratory began patient testing in May 2023 and confirmed testing personnel did not test two levels of control materials each day of patient testing and confirmed the technical consultant had not developed an IQCP for the Afinion 2 analyzers.
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 surveyor review of procedures and competence evaluation records and interview with the director of medical services, the technical consultant did not evaluate the competence of seven of seven testing personnel using the six elements required in 493.1413(b)(8)(i-vi) and in the laboratory's procedures. Findings include: 1. Review of the procedure, 'Laboratory Competency Assessment Policy' showed "the evaluator for non-waived testing will be the technical consultant". Further review showed the procedure required use of six methods to evaluate competence including: Direct observation of routine test performance. Monitoring the recording and reporting of test results. Review of intermediate test results or worksheets, quality

	control records, proficiency test results, and preventative maintenance records. Direct observation of the performance of instrument maintenance and function checks including quality control, calibration, and routine maintenance. Assessment of test performance through testing previously analyzed specimens, internal blind test samples or external proficiency test samples. Assessment of problem-solving skills. 2. Review of competence evaluation records including 'Medical Assistant Lab Skills' and 'Medical Assistant / Lab Competency Checklist' forms showed all forms identified testing personnel (staff C or staff G) as the "Trainer / Observer". No records showed the technical consultant performed any competence evaluations of testing personnel. The forms showed no documentation confirming use of the six methods to evaluate competence. 3. Interview with the director of medical services (staff B) on July 19, 2023, at 10:45 AM confirmed the technical consultant did not evaluate competence of testing personnel and confirmed staff did not include the six elements in competence evaluation. Further interview confirmed testing personnel staff C and G were not qualified to evaluate competence of non-waived testing personnel.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on surveyor review of personnel records and interview with the director of medical services, the laboratory had not obtained credentials for six of seven testing personnel to show they were qualified to perform moderate complexity testing. Findings include: 1. The laboratory could not show six of seven testing personnel met the qualification requirements for moderate complexity testing. See D6065.
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on surveyor review of the Centers for Medicare and Medicaid Services (CMS) Form CMS-209 'Laboratory Personnel Report (CLIA)' and personnel records, and interview with the director of medical services, six of seven non-waived testing personnel did not have documented evidence showing they met the qualification requirements to perform moderate complexity testing. Findings include: 1. Review of

	the Form CMS-209 submitted for this survey and signed by the laboratory director on July 11, 2023, showed the laboratory had seven non-waived testing personnel. 2. Review of personnel records showed no evidence six of the seven testing personnel met the academic requirements for non-waived testing personnel. Records for Staff C included a high school diploma. 3. Interview with the director of medical services (staff B) on July 19, 2023, at 10:45 AM confirmed credentials were not available showing staff D, E, F, G, H, and I met the requirements for moderate complexity testing personnel.