Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2311307	05/22/2026
Name of Provider or Supplier	**Street Address, City, State**	
Wi Care Clinical Labs Llc	6100 K Avenue Suite 108, Plano, TX	

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
D0000	An initial survey was completed on 05/22/2026. Immediate Jeopardy exists for the following condition level deficiencies: 42 C.F.R. 493.801 Condition: Enrollment and Testing of Samples 42 C.F.R. 493.1250 Condition: Analytic Systems 42 C.F.R. 493.1403 Condition: Moderate Complexity Laboratory Director 42 C.F.R. 493.1415 Condition: Clinical Consultant
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 review of policies and procedures for "General SOPS", review of the binder titled "College of American Pathologists (CAP) Accreditation Documents", review of laboratory test records, and an interview with the Laboratory Director (LD), the laboratory failed to enroll in a proficiency testing (PT) program for complete blood count (CBC) testing in the specialty of Hematology. This deficient practice affected one out of one patient tested in the specialty of Hematology from 02/12/2026 through 05/19/2026, with the potential to affect an undetermined number of future patients. Findings include: 1. The laboratory failed to enroll in a PT program for CBC testing performed in the specialty of Hematology. (Refer to D2001)
D2001	ENROLLMENT

	CFR(s): 493.801(a)(1)(2)(i) The laboratory must-- (1) Notify HHS of the approved program or programs in which it chooses to participate to meet proficiency testing requirements of this subpart. (2)(i) Designate the program(s) to be used for each specialty, subspecialty, and analyte or test to determine compliance with this subpart if the laboratory participates in more than one proficiency testing program approved by CMS; and This STANDARD is not met as evidenced by: Based on review of policies and procedures for "General SOPS", review of the binder titled "College of American Pathologists (CAP) Accreditation Documents", review of laboratory test records, and an interview with the Laboratory Director (LD), the laboratory failed to enroll in a proficiency testing (PT) program which contained five test specimens in three annual testing events for moderate complex complete blood count (CBC) testing performed in the specialty of Hematology. This deficient practice affected one out of one patient tested in the specialty of Hematology from 02/12/2026 through 05/19/2026, with the potential to affect an undetermined number of future patients. Findings include: 1. A review of the "General SOPS" approved by the LD on 01/23/2026, and provided on the date of the inspection, lacks any mention of PT policies and procedures. 2. Review of the binder titled "College of American Pathologists (CAP) Accreditation Documents" does not contain any enrollment documentation or CAP test event documents. 3. In an interview on 05/19/2026 at 11: 30 AM, the inspector requested the laboratory's 2026 CAP PT documentation of CBC enrollment and testing from the LD. The LD confirmed the laboratory had not enrolled in PT and could not provide the requested documents. 4. Review of the laboratory records revealed one of one patient CBC tested, patient identification number 1164911, in the specialty of Hematology from 02/12/2026 through 05/19 /2026.
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 the review of the policy and procedure titled "Quality Procedure for Validation", review of the Beckman Coulter DXH520 instrument quality control records, review of patient test results, and an interview with the Laboratory Director (LD), the laboratory failed to monitor and evaluate the overall quality of the analytic systems and correct identified problems with the moderate complex complete blood count (CBC) testing procedures in the specialty of Hematology and the waived urine drug screen (UDS) testing procedures in the subspecialty of Toxicology. This deficient practice had the potential to affect one of one patient Hematology testing procedure and one of one patient Toxicology testing procedure from 02/12/2026 through 05/19/2026, and an undetermined number of future patients tested. Findings Include: 1. The laboratory failed to follow written procedures for instrument

	validation. (Refer to D5401) 2. The laboratory lacked documentation for reportable ranges, the ranges for imminent life-threatening test results, and/or the panic or alert value ranges for the test system. (Refer to D5403). 3. The laboratory failed to ensure control materials were not used when they had exceeded their expiration date. (Refer to D5217)
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (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 the review of the policy and procedure titled "Quality Procedure for Validation", review of patient test results, and an interview with the Laboratory Director (LD), the laboratory failed to follow their policy and procedure for validation of the FormFox Flex test system utilized for urine drug screen (UDS) testing in the subspecialty of Toxicology. This deficient practice had the potential to affect one of one patient Toxicology testing procedure from 02/12/2026 through 05/19/2026 and an undetermined number of future patients tested. Findings Include: 1. Review of the policy and procedure titled "Quality Procedure for Validation", approved via signature and date by the LD on 11/06/2025, and provided the date of the inspection, found the following statements: "1) Develop validation plans using predefined template which contains but not limited to, the following: ...iv. Test scenarios. Testing will be performed in a manner to ensure, in a complete, verifiable manner, the requirements, design, and characteristics of the system and its components. ...viii. System acceptance- Final report. A formal system acceptance document, consisting of review and acceptance of the completed/tested system and validation documentation, will be performed to ensure that the expectations laid out in the plan have been fulfilled." 2. On 05/19/2026 at 12:30 PM, the surveyor requested the validation records for the FormFox Flex urine drug screening instrument from the LD. The LD stated the instrument was not in use, and there were no validation records for the FormFox Flex UDS instrument. 3. Review of patient test reports revealed one "Rapid non-DOT Urine Drug Screen" laboratory test requisition for specimen #CC19715250, with attached test panel results for 6-acetylmorphine, barbiturates, buprenorphine, fentanyl, 3,4-methylenedioxymethamphetamine (MDMA), methamphetamine, oxycodone, amphetamines, benzodiazepines, cocaine metabolites, marijuana metabolite, methadone, opiates, and phencyclidine dated 03/30/2026 at 3:23 PM.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification

procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's policies and procedures titled "General SOPS", review of patient test results, and an interview with the Laboratory Director (LD), the laboratory failed to include the reportable ranges and imminently life-threatening test results, panic or alert values for the 14-panel urine drug screen (UDS) test results, the complete metabolic panel (CMP) test results, and the complete blood count (CBC) test results. This deficient practice had the potential to affect one of one patient Hematology testing procedure, and one of one patient Toxicology testing procedure from 02/12/2026 through 05/19/2026 and an undetermined number of future patients tested. Findings include: 1. Review of the laboratory's policies and procedures titled "General SOPS" signed and dated by the Laboratory Director on 01/23/2026, failed to find a policy and procedure that included the reportable ranges and imminently life-threatening test results, panic or alert values for 6-acetylmorphine, barbiturates, buprenorphine, fentanyl, 3,4-methylenedioxymethamphetamine (MDMA), methamphetamine, oxycodone, amphetamines, benzodiazepines, cocaine metabolites, marijuana metabolite, methadone, opiates, and phencyclidine test results for the FormFox Flex UDS test system. 2. Review of the laboratory's policies and procedures titled "General SOPS" signed and dated by the Laboratory Director on 01/23/2026 failed to find reportable ranges and imminently life-threatening test results, panic or alert values for red blood cell Count (RBC), hemoglobin (Hgb/Hb), hematocrit (Hct), mean corpuscular volume (MCV), mean corpuscular hemoglobin (MCH), mean corpuscular hemoglobin concentration (MCHC), red cell distribution width (RDW), white blood cell count (WBC), white blood cell differential, neutrophils, lymphocytes, monocytes, eosinophils, basophils, platelet count (PLT), mean platelet volume (MPV), platelet distribution width (PDW), neutrophils (absolute), lymphocytes (absolute), monocytes (absolute), eosinophils (absolute), basophils (absolute) test results for the Beckman Coulter DXH520 test system. 3. Review of the laboratory's policies and procedures titled "General SOPS" signed and dated by the Laboratory Director on 01/23/2026 of the laboratories policies and procedures failed to find reportable ranges and imminently life-threatening test results, panic or alert values for glucose (GLU), blood urea nitrogen (BUN), creatinine (CREA), sodium (NA), potassium (K), chloride (CL), carbon dioxide (CO2), calcium (CA), alanine aminotransferase (ALT / SGPT), aspartate aminotransferase (AST / SGOT), alkaline phosphatase (ALP), total bilirubin (TBIL), total protein (TP), and albumin (ALB) for the Beckman Coulter AU480 test system. 4. Review of one of one available patient test report, found CMP and CBC test results for patient identification number 1164911, and one of one available patient test report for UDS for patient identification number T25164954, from 02/12/2026 through 05/19/2026. 5. On 05/19 /2026, at 2:30 PM, the inspector requested the policy and procedure listing the reportable ranges and imminently life-threatening test results, panic or alert values for the UDS, CMP, and CBC test analytes from the LD. The LD confirmed the laboratory

	did not have a policy and procedure listing the reportable ranges and imminently life-threatening test results, panic or alert values for the UDS, CMP, and CBC tests.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (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 review of the laboratory's policy and procedure titled "General SOPS", review of the Beckman Coulter DXH520 instrument quality control records, review of patient test results, and an interview with the Laboratory Director (LD), the laboratory failed to ensure quality controls utilized for the testing of moderate complexity complete blood count (CBC) tests were not used when they had exceeded their expiration dates. This deficient practice had the potential to affect one of one patient Hematology testing procedure from 02/12/2026 through 05/19/2026 and undetermined number of future patients tested. Findings Include: 1. Review of the laboratory's policy and procedure titled "General SOPS" approved by the LD via signature and date on 01/23/2026, and provided on the date of inspection, revealed the following statement: "5.2.7 Expired Reagents d) Expired calibrators & controls may under no circumstances be used." 2. Review of the Beckman Coulter DXH520 instrument quality control records revealed the following: Run Date Lot Expiration 05 /05/2026- 362618212 05/05/2026 05/08/2026 352618211 05/05/2026 372618213 05 /05/2026 05/11/2026- 362618212 05/05/2026 05/15/2026 352618211 05/05/2026 372618213 05/05/2026 05/18/2026 362618212 05/05/2026 352618211 05/05/2026 372618213 05/05/2026 3. Review of the Beckman Coulter DXH520 patient CBC test reports found one out of one patient report, patient #1164911, dated 05/07/2026. 4. In an interview on 05/19/2026 at 2:45 PM, the LD confirmed that the quality controls utilized on the Beckman Coulter DXH520 from 05/05/2026 - 05/08/2026, 05/11/2026 - 05/15/2026, and 05/18/2026 were expired.
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 review of the laboratory's forms CMS-116 and CMS-209, review of education documentation, review of Curriculum Vitae (CV) records, review of policy and procedures for "Quality Procedure for Handling Nonconformances" and "General SOPS", review of the Beckman Coulter DXH520 instrument quality control records and test results, and an interview with the Laboratory Director (LD), the LD failed to meet the qualification requirements of 493.1405 of this subpart and provide overall management and direction in accordance with 493.1407 of this subpart to ensure that the quality control (QC) and quality assessment (QA) programs were established and maintained to assure the quality of the moderate complexity complete blood count (CBC) testing, and to identify failures in quality as they occur. This deficient practice

	had the potential to affect three out of three patients tested at this laboratory from 02 /12/2026 through 05/19/2026 and an undetermined number of future patients. Findings include: 1. Review of the CMS-116 and CMS-209 forms, provided on 04/07 /2026, found one individual listed as the Laboratory Director. Review of educational records found that the LD failed to meet the qualification requirements of 493.1405 of this subpart. (Refer to D6003). 2. The laboratory director failed to ensure that the quality control and quality assessment programs were established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. (Refer to D6020.)
D6003	LABORATORY DIRECTOR QUALIFICATIONS CFR(s): 493.1405 AND 493.1406 The laboratory director must be qualified to manage and direct the laboratory personnel and the performance of moderate complexity tests and must be eligible to be an operator of a laboratory within the requirements of subpart R of this part. (a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required; and (b) The laboratory director 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 (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 had laboratory training or experience consisting of: (b)(2)(ii)(A) At least one year directing or supervising non-waived laboratory testing; and (b)(2)(ii)(B) Have at least 20 CE credit hours in laboratory practice that cover the laboratory director responsibilities defined in 493. 1407; or (b)(3)(i)(A) Hold an earned doctoral degree in a chemical, biological, clinical or medical laboratory science or medical technology from an accredited institution; or (b)(3)(i)(B) Hold an earned doctoral degree; and (b)(3)(i)(B)(1) Have at least 16 semester hours of doctoral level coursework in biology, chemistry, medical technology (MT), clinical laboratory science (CLS), or medical laboratory science (MLS); or (b)(3)(i)(B)(2) An approved thesis or research project in biology/chemistry /MT/CLS/MLS related to laboratory testing for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings; and (b)(3)(ii) Have at least 20 CE credit hours in laboratory practice that cover the laboratory director responsibilities defined in 493.1407; and (b)(3)(ii)(A) Be certified and continue to be certified by a board approved by HHS; and (b)(3)(ii)(B) Have had at least 1 year of experience directing or supervising nonwaived laboratory testing; or (b)(4)(i)(A) Have earned a master's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(4)(i)(B)(1) Meet bachelor's degree equivalency; and (b)(4)(i)(B)(2) Have at least 16 semester hours of additional graduate level coursework in biology, chemistry, medical technology, clinical or medical laboratory science; or (b)(4)(i)(C)(1) Meet bachelor's degree equivalency; and (b)(4)(i)(C)(2) Have at least 16 semester hours in a combination of graduate level coursework in biology, chemistry, medical technology, clinical or medical laboratory science coursework and an approved thesis or research project related to laboratory testing for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings; and (b)(4) (ii) Have at least 1 year of laboratory training or experience, or both, in nonwaived testing; and (b)(4)(iii) Have at least 1 year of supervisory laboratory experience in nonwaived testing; and (b)(4)(iv) Have at least 20 CE credit hours in laboratory

	practice that cover the director responsibilities defined in 493.1407; or (b)(5)(i)(A) Have earned a bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(5)(i)(B) At least 120 semester hours, or equivalent, from an accredited institution that, at a minimum, includes either- (b)(5)(i)(B)(1) 48 semester hours of medical laboratory science or medical laboratory technology courses; or (b)(5)(i)(B)(2) 48 semester hours of science courses that include- (b)(5)(i)(B)(2)(i) 12 semester hours of chemistry, which must include general chemistry and biochemistry or organic chemistry; and (b)(5)(i)(B)(2)(ii) 12 semester hours of biology, which must include general biology and molecular biology, cell biology or genetics; and (b)(5)(i)(B)(2)(iii) 24 semester hours of chemistry, biology, or medical laboratory science or medical laboratory technology in any combination; and (b)(5)(ii) Have at least 2 years of laboratory training or experience, or both, in nonwaived testing; and (b)(5)(iii) Have at least 2 years of supervisory laboratory experience in nonwaived testing; and (b)(5)(iv) Have at least 20 CE credit hours in laboratory practice that cover the director responsibilities defined in 493.1407. (b)(6) Notwithstanding any other provision of this section, an individual is considered qualified as a laboratory director of moderate complexity testing under this section if they were qualified and serving as a laboratory director of moderate complexity testing in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024. This STANDARD is not met as evidenced by: Based on review of the laboratory's forms CMS-116 and CMS-209, review of education documentation, review of Curriculum Vitae (CV) records, and an interview with the Laboratory Director (LD), the LD failed to meet the qualification requirements of 493.1405 of this subpart. for a moderate complexity LD. This deficient practice had the potential to affect all patients tested at this laboratory from 02/12/2026 through 05/19/2026 and an undetermined number of future patients. Findings include: 1. Review of the CMS-116 and CMS-209 forms, provided on 04/07/2026, found one individual listed as the Laboratory Director. 2. Review of education records provided on 04/07/2026 found the LD had earned a Bachelor of Science in Medical Laboratory Technology. 3. Review of the Curriculum Vitae (CV) record did not find supporting documentation of at least two years directing or supervising a non-waived laboratory, at least 20 continuing education credit hours in laboratory practice that cover the LD responsibilities as defined in 493.1407, and a U.S. Department of Health and Human Services (HHS) board-approved certification. 4. In an interview on 05/19/2026 at 10:00 AM with the LD confirmed that he did not have the above-mentioned documents and did not meet the qualifications requirements of 493.1405 for a moderate complexity LD.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur; This STANDARD is not met as evidenced by: Based on review of policy and procedures for "Quality Procedure for Handling Nonconformances" and "General SOPS", review of the Beckman Coulter DXH520 instrument quality control records and test results, and an interview with the

	Laboratory Director (LD), the LD failed to ensure that the quality control (QC) and quality assessment (QA) programs were established and maintained to assure the quality of the moderate complexity complete blood count (CBC) testing, and to identify failures in quality as they occur. This deficient practice had the potential to affect 21 out of 21 analytes tested in the specialty of Hematology from 05/05/2026 through 05/18/2026. Findings include: 1. Review of the laboratory's policy and procedure titled "Quality Procedure for Handling Nonconformances" approved via signature and date on 11/18/2025 by the LD stated: "1. Assess the severity of the nonconformance and classify as minor or major by using Minor deviations form and above definitions. 2. If it is a minor deviation, initiate the minor deviation form 3. Select all appropriate deviations topics that best describe the nonconformity being tracked 4. Take immediate correction, if applicable and record on minor deviation form" 2. Review of the laboratory's policy and procedure titled "General SOPS" approved by the LD via signature and date on 01/23/2026, and provided on the date of inspection stated: "5.2.7 Expired Reagents d) Expired calibrators & controls may under no circumstances be used." 3. Review of the Beckman Coulter DXH520 instrument quality control records revealed the following: Run Date Lot Expiration 05 /05/2026- 362618212 05/05/2026 05/08/2026 352618211 05/05/2026 372618213 05 /05/2026 05/11/2026- 362618212 05/05/2026 05/15/2026 352618211 05/05/2026 372618213 05/05/2026 05/18/2026 362618212 05/05/2026 352618211 05/05/2026 372618213 05/05/2026 3. Further review of the Beckman Coulter DXH520 instrument quality control records revealed the LD approval via initials and date, and the handwritten statement "QC Passed". 4. Review of the Beckman Coulter DXH520 patient CBC test reports found one out of one patient report, patient # 1164911, dated 05/07/2026. 5. Review of the moderate complexity complete blood count (CBC) testing included red blood cell count, hemoglobin, hematocrit, mean corpuscular volume, mean corpuscular hemoglobin, mean corpuscular hemoglobin concentration, red cell distribution width, white blood cell count, white blood cell differential, neutrophils, lymphocytes, monocytes, eosinophils, basophils, platelet count, mean platelet volume, platelet distribution width, neutrophils, lymphocytes, monocytes, eosinophils, and basophils. 6. An interview on 05/19/2026 at 2:30 PM, the LD confirmed the quality controls utilized on the Beckman Coulter DXH520 from 05/05 /2026 - 05/08/2026; 05/11/2026 - 05/15/2026; and 05/18/2026 were expired and could not provide documentation assuring the quality of the CBC patient test report.
D6056	CLINICAL CONSULTANT CFR(s): 493.1415 The laboratory must have a clinical consultant who meets the qualification requirements of 493.1417 of this part and provides clinical consultation in accordance with 493.1419 of this part. This CONDITION is not met as evidenced by: Based on review of the laboratory's form CMS-209, review of education documentation, and an interview with the Laboratory Director (LD), the Clinical Consultant (CC) failed to meet the qualification requirements of 493.1417 of this subpart. This deficient practice had the potential to affect all patients tested at this laboratory from 02/12/2026 through 05/19/2026 and an undetermined number of future patients. Findings include: 1. Review of the form CMS-209 provided on 04/07 /2026 found one out of one individual listed and qualified by the LD via signature and

	date on 04/07/2026 to serve as the CC. Review of education records provided on 04/07/2026 found the CC did not meet the qualification requirements of 493.1417. (Refer to D6057)
D6057	CLINICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1417 The clinical consultant must be qualified to consult with and render opinions to the laboratory's clients concerning the diagnosis, treatment and management of patient care. The clinical consultant must-- (a) Be qualified as a laboratory director under 493.1405(b)(1), (2), or (3); or (b) Be a doctor of medicine, doctor of osteopathy or doctor of podiatric medicine and possess a license to practice medicine, osteopathy or podiatry in the State in which the laboratory is located. This STANDARD is not met as evidenced by: Based on review of the laboratory's form CMS-209, review of education documentation, and an interview with the Laboratory Director (LD), the Clinical Consultant (CC) failed to meet the qualification requirements of 493.1417 of this subpart. This deficient practice had the potential to affect all patients tested at this laboratory from 02/12/2026 through 05/19/2026 and an undetermined number of future patients. Findings include: 1. Review of the form CMS-209 provided on 04/07/2026 found one out of one individual listed and qualified by the LD via signature and date on 04/07/2026 to serve as the CC. 2. Review of education records provided on 04/07/2026 found the CC had a Master of Science Degree in Clinical Biochemistry, which did not meet the qualification requirements of 493.1417. 3. On 05/19/2026 at 10:10 AM, the LD confirmed the CC did not meet the requirements of 493.1417.