Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D2242011	05/15/2023
Name of Provider or Supplier	**Street Address, City, State**	
Ak Diagnostic Laboratory Llc	35540 W Michigan Avenue, Wayne, MI	

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 record review and interview with the Laboratory Director, the laboratory failed to enroll in an approved proficiency testing program for its regulated analytes for 15 (5/1/23 to 5/15/23) of 15 days since the laboratory had started testing 5/1/23. Findings include: 1. An interview with the Laboratory Director on 5/15/23 at 10:00 am revealed the laboratory started testing on 5/1/23. 2. A review of the laboratory's test menu revealed the following regulated analytes: a. Alanine Aminotransferase (ALT) b. Albumin c. Alkaline Phosphatase d. Aspartate Aminotransferase (AST) e. Bilirubin, total f. Calcium, total g. Chloride h. Cholesterol, total i. Cholesterol, HDL j. Creatinine k. Glucose l. Potassium m. Sodium n. Total Protein o. Triglycerides p. Blood Urea Nitrogen (BUN) q. Thyroid Stimulating Hormone 3. A review of email correspondence provided by the laboratory with a proficiency testing program revealed a lack of enrollment. 4. The surveyor requested documentation showing enrollment in a proficiency testing program on 5/15/23 at 10:25 am and it was not made available. 5. An interview on 5/15/23 at 1:32 pm with the Laboratory Director confirmed documentation showing the laboratory had enrolled in an approved proficiency testing program was not available.

D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: . Based on observation, record review, and interview with the Laboratory Director, the laboratory failed to observe its established safety procedures for 15 (5/1/23 to 5/15/23) of 15 days since the laboratory had started testing 5/1/23. Findings include: 1. The surveyor observed an eye wash squeeze bottle in the breakroom down the hall from the laboratory that contained clear fluid and no indication of an expiration date. 2. An interview on 5/15/23 at 10:37 am with the Laboratory Director revealed the bottle was filled with tap water about a week ago and had been sitting at room temperature in the breakroom area since it was filled. 3. A review of the laboratory's Eyewash Procedure and Log" revealed a section stating, "Bacterial and parasitic organisms are ubiquitous in tap water. In most instances, the number of organisms will not be significant, but they proliferate in stagnant, residual water and then become dangerous" and "In general, squeeze bottles should not be used, except where the hazard severity, or distance from plumbed eyewash equipment requires personal equipment at workstations for immediate flushing at aplumbed or self-contained unit" and "For emergency eyewash stations to be effective. The affected eye(s) must be flushed immediately and thoroughly for at least 15 minutes using a large supply of clean fluid under low pressure." 4. A review of the laboratory's "Electrical and Mechanical Safety Plan" revealed a section titled "Emergency Equipment: Eye Wash" stating, "Any employee coming in contact with any hazardous material will be oriented to the actual chemicals and emergency equipment in use in the laboratory. Training for Emergency Equipment: a. This is the responsibility of the Supervisor. b. The training is to be documented on the Employee Training Log. c. The original training record goes to the staff file. A copy may be given to the employee. "Eye Wash stations are verified weekly for operation by checking that: i. The devices stay on without using hands ii. Eye wash nozzles are covered. Caps are intact and clean iii. The height of the stream of water is to be 3-6 inches to assure correct pressure. iv. Water temperatures are to be tepid. v. Access is within 10 seconds from hazard, and not obstructed. vi. Document the actions on the eye wash testing log." 5. An interview on 5/15/23 at 1:32 pm with the Laboratory Director confirmed the laboratory had not followed its established safety policies regarding the eye wash station.
D5016	ROUTINE CHEMISTRY CFR(s): 493.1210 If the laboratory provides services in the subspecialty of Routine Chemistry, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493. 1267, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: . Based on observations, record review, and interviews, the laboratory failed to ensure test requests included the date and time of specimen collection (Refer to D5305), failed to establish written policies and procedures for specimen storage, preservation, conditions for specimen transportation, and specimen referral (Refer to D5311), failed

	to establish test procedures for its chemistry testing (Refer to D5401), failed to label its control materials with the expiration dates reflecting their stability once reconstituted (Refer to D5415), and failed to establish criteria to verify the calibration verification performed on the Horiba Pentra 400 chemistry analyzer (Refer to D5439).
D5020	ENDOCRINOLOGY CFR(s): 493.1212 If the laboratory provides services in the subspecialty of Endocrinology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: . Based on observations, record review, and interviews, the laboratory failed to ensure test requests included the date and time of specimen collection (D5305), failed to establish written policies and procedures for specimen storage, preservation, conditions for specimen transportation, and specimen referral (Refer to D5311), failed to establish test procedures for its endocrinology testing (Refer to D5401), failed to label its control materials with the expiration dates reflecting their stability once reconstituted (Refer to D5415), and failed to ensure test reports for its patient testing completed using the Beckman Coulter Access 2 immunoassay analyzer were issued to the ordering provider (Refer to D5801).
D5305	TEST REQUEST CFR(s): 493.1241(c) The laboratory must ensure the test requisition solicits the following information: (1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. (2) The patient's name or unique patient identifier. (3) The sex and age or date of birth of the patient. (4) The test(s) to be performed. (5) The source of the specimen, when appropriate. (6) The date and, if appropriate, time of specimen collection. (7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. (8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable. This STANDARD is not met as evidenced by: . Based on record review and interview with the Laboratory Director, the laboratory failed to ensure test requests included the date and time of specimen collection for 7 (Patients 54926, 54970, 54971, 55009, 55019, 55059, and 55010) of 7 patient test records reviewed. Findings include: 1. An interview on 5/15/23 at 11:55 am with the Laboratory Director revealed the laboratory has one client and it is a home health agency that collects specimens within the patients' homes. 2. A review of patient test requisitions revealed the following patients tested on 5/10/23 and 5/12/23 had not had the date and time of specimen collection indicated: a. Patient 54926 b. Patient 54970 c. Patient 54971 d. Patient 55009 e. Patient 55019 f. Patient 55059 g. Patient 55010 3. An interview on 5/15/23 at 12:40 pm with the Laboratory Director confirmed the

	laboratory had not ensured the time and date of collection had been indicated on the test requests for the patients listed above.
D5309	TEST REQUEST CFR(s): 493.1241(e) If the laboratory transcribes or enters test requisition or authorization information into a record system or a laboratory information system, the laboratory must ensure the information is transcribed or entered accurately. This STANDARD is not met as evidenced by: . Based on record review and interview with the Laboratory Director, the laboratory failed to ensure test requests transcribed included a request for direct low-density lipoprotein (LDL) testing for 6 (Patients 54926, 54970, 54971, 55009, 55059, and 55010) of 6 patients with an order for testing. Findings include: 1. A review of the 6 patient test records revealed the following patients had direct LDL testing listed on the test request: a. Patient 54926 b. Patient 54970 c. Patient 54971 d. Patient 55009 e. Patient 55059 f. Patient 55010 2. A review of the laboratory's patient test reports listed above revealed a lack of direct LDL results. 3. An interview on 5/15/23 at 1:32 pm with the Laboratory Director confirmed the laboratory had not accurately transcribed test requests to its reference laboratory to include all testing ordered.
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 record review and interview with the Laboratory Director, the laboratory failed to establish written policies and procedures for specimen storage, preservation, conditions for 15 (5/1/23 to 5/15/23) of 15 days since the laboratory had started testing 5/1/23. Findings include: 1. An interview on 5/15/23 at 11:55 am with the Laboratory Director revealed the laboratory has one client and it is a home health agency that collects specimens within the patients' homes. 2. A review of the laboratory's procedure manual revealed a lack of established written policies and procedures for specimen storage, preservation, conditions for specimen transportation, and specimen referral. 3. An interview on 5/15/23 at 11:28 am with the Laboratory Director confirmed the laboratory had not established written policies and procedures for specimen storage, preservation, conditions for specimen transportation, and specimen referral.
D5313	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(b) The laboratory must document the date and time it receives a specimen.

	This STANDARD is not met as evidenced by: . Based on record review and interview with the Laboratory Director, the laboratory failed to document the time it received specimens for 7 (Patients 54926, 54970, 54971, 55009, 55019, 55059, and 55010) of 7 patient test records reviewed. Findings include: 1. An interview on 5/15/23 at 11:55 am with the Laboratory Director revealed the laboratory has one client and it is a home health agency that collects specimens within the patients' homes and delivers the specimens to the laboratory. 2. A review of 7 patient test records revealed the laboratory failed to document the time the laboratory received specimens for the following patients tested on 5/10/23 and 5/12 /23: a. Patient 54926 b. Patient 54970 c. Patient 54971 d. Patient 55009 e. Patient 55019 f. Patient 55059 g. Patient 55010 3. An interview on 5/15/23 at 1:32 pm with the Laboratory Director confirmed the laboratory had not documented the time it received specimens.
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 record review and interview with the Laboratory Director, the laboratory failed to establish test procedures for its chemistry and endocrinology testing for 15 (5 /1/23 to 5/15/23) of 15 days since the laboratory had started testing 5/1/23. Findings include: 1. A review of the laboratory's policies and procedures revealed a lack of test procedures for chemistry and endocrinology testing using their Horiba Pentra 400 and Beckman Coulter Access 2 analyzers. 2. An interview on 5/15/23 at 11:43 am with the Laboratory Director confirmed the laboratory had not established test procedures for its chemistry and endocrinology testing.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: . Based on record review and interview with the Laboratory Director, the laboratory failed to label its control materials with the expiration dates reflecting their stability once reconstituted for 4 (Bo-Rad Lyphochek Immunoassay Plus Levels 1 and 3 and ABX Pentra Multicontrol Levels 1 and 2.) of 4 control materials observed. Findings include: 1. The surveyor observed two sets of reconstituted control materials used in chemistry and endocrinology testing in the laboratory's refrigerator during a tour on 5 /15/23 at 10:15 am with the following information: a. ABX Pentra Multcontrol level 1 and 2 with 5/12/23 listed as the date of reconstitution. b. Lyphochek Immunoassay

	Plus level 1 and 3 with 5/12/23 listed as the date of reconstitution. 2. An interview with the Laboratory Director on 5/15/23 at 10:15 am revealed the controls that had been reconstituted were stable 30 days. 3. A review of the laboratory's "ABX Pentra N MultiControl" manufacturer's instructions revealed a section stating, a. "Stability after reconstitution: i. 12 hours at 15 - 25C ii. 5 days at 2 - 8C iii. 28 days at (-15) - (-25)C b. Stability of total bilirubin and direct bilirubin after reconstitution: i. 8 hours at 15 - 25C ii. 24 hours at 2 - 8C iii. 14 days at (-15) - (-25)C c. Stability of ALT after reconstitution: i. 12 hours at 15 - 25C ii. 5 days at 2 - 8C iii. 14 days at (-15) - (-25)C" 4. A review of the laboratory's "Bio-Rad Lyphochek Immunoassay Plus Control Levels 1, 2 and 3" manufacturer's instructions revealed a section titled "Reconstituted and Refrigerated" stating, "After reconstituting and storing tightly capped at 2 to 8 degrees C, this product will be stable as follows: a. All analytes: 7 days b. Except: Folate and PSA (Total): 3 days at 2 to 8 degrees C." 5. An interview on 5/15/23 at 1: 32 pm with the Laboratory Director confirmed the controls listed above had not been labeled with the expiration date reflecting their reconstituted stability.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: . Based on record review and interview with the Laboratory Director, the laboratory failed to establish criteria to assess the acceptability of calibration verification performed on the Horiba Pentra 400 chemistry analyzer for 1 (5/10/23) of 1 calibration verification event performed since the laboratory started testing. Findings include: 1. A review of the laboratory's calibration verification documentation performed on 5/10/23 revealed the raw data from 5 samples. 2. The surveyor requested the laboratory's calibration verification acceptability criteria and the standard values from the linearity standard samples on 5/15/23 at 12:13 pm and it was not made available. 3. An interview on 5/15/23 at 12:13 pm with the Laboratory Director revealed the laboratory had not established acceptability criteria and had not assessed the data from the 5 calibration verification samples that had been tested on 5 /10/23.

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 record review and interview with the Laboratory Director, the laboratory failed to ensure test reports for its patient testing completed using the Beckman Coulter Access 2 immunoassay analyzer were issued to the ordering provider for 24 of 24 patients performed since testing began. Findings include: 1. A review of patient test records revealed a lack of patient test reports for the 24 patients receiving vitamin D, total PSA, and Thyroid Stimulating Hormone (TSH) testing using the Beckman Coulter Access 2 analyzer. 2. An interview on 5/15/23 at 1:32 pm with the Laboratory Director revealed the laboratory had not provided the ordering provider test reports for its testing completed using the Beckman Coulter Access 2 analyzer.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: . Based on record review, observation, and interviews, the Laboratory Director failed to ensure established safety procedures for its eye wash station were observed (Refer D6011), failed to ensure criteria to assess the acceptability of calibration verification performed on the Horiba Pentra 400 chemistry analyzer was established (Refer to D6013), failed to ensure enrollment in an approved proficiency testing program for its regulated analytes (Refer to D6015), failed to ensure test reports for its patient testing completed using the Beckman Coulter Access 2 immunoassay analyzer were issued to the ordering provider (Refer to D6026), failed to ensure the Technical Consultant had met the qualification requirements at 493.1411 (Refer to D6028 A), and failed to employ a qualified clinical consultant (Refer to D6028 B).
D6011	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(2) 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)(2) and provide a safe environment in which employees are protected from physical, chemical, and biological hazards.

	This STANDARD is not met as evidenced by: . Based on observation, record review and interview with the Laboratory Director, the Laboratory Director failed to ensure established safety procedures for its eye wash station were observed. Refer to D3011.
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 record review and interview with the Laboratory Director, the Laboratory Director failed to ensure criteria to assess the acceptability of calibration verification performed on the Horiba Pentra 400 chemistry analyzer was established. Refer to D5439.
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 record review and interview with the Laboratory Director, the Laboratory Director failed to ensure enrollment in an approved proficiency testing program for its regulated analytes. Refer to D2000.
D6026	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(8) 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)(8) Ensure that reports of test results include pertinent information required for interpretation. This STANDARD is not met as evidenced by:

	. Based on record review and interview with the Laboratory Director, the Laboratory Director failed to ensure test reports for its patient testing completed using the Beckman Coulter Access 2 immunoassay analyzer were issued to the ordering provider. Refer to D5801.
D6028	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(10) 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)(10) Employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart; This STANDARD is not met as evidenced by: . A. Based on record review and interview with the Laboratory Director, the Laboratory Director failed to ensure the Technical Consultant had met the qualification requirements at 493.1411. Refer to D6035. B. Based on record review and interview with the Laboratory Director, the Laboratory Director failed to employ a qualified clinical consultant. Refer to D6057.
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: . A. Based on record review and interview with the Laboratory Director, The Laboratory Director failed to ensure written policies and procedures for specimen storage, preservation, conditions for specimen transportation, and specimen referral were established and approved. Refer to D5311. B. Based on record review and interview with the Laboratory Director, the Laboratory Director failed to ensure written test procedures for its chemistry and endocrinology testing were established and approved. Refer to D5401.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.

	This CONDITION is not met as evidenced by: . Based on record review and interview with the Laboratory Director, the laboratory failed to ensure Technical Consultant had met the qualification requirements at 493.1411. Refer to D6035.
D6035	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 (a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service. This STANDARD is not met as evidenced by: . Based on record review and interview with the Laboratory Director, the laboratory failed to ensure Technical Consultant had met the qualification requirements at 493.1411 for 1 of 1 Technical Consultant listed on Form CMS-209. Findings include: 1. A review of the laboratory's Form CMS-209 revealed the Laboratory Director was also serving as the Technical Consultant. 2. A review of the laboratory's personnel files revealed a lack of documentation of at least 1 year of laboratory training or experience in the subspecialties of routine chemistry and endocrinology. 3. An interview on 5/15/23 at 12:53 pm with the Laboratory Director confirmed documentation to qualify as a Technical Consultant for routine chemistry and

	endocrinology was not present. 4. The laboratory was given an additional 7 days to provide documentation showing the Technical Consultant met the qualification requirements and it was not made available.
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 record review and interview with the Laboratory Director, the laboratory failed to employ a qualified clinical consultant. 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)(i); 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 record review and interview with the Laboratory Director, the laboratory failed to employ a qualified clinical consultant for for 15 (5/1/23 to 5/15/23) of 15 days since the laboratory had started testing 5/1/23. Findings include: 1. A review of the laboratory's personnel records revealed a lack of documentation showing any laboratory personnel were qualified or serving the role of clinical consultant. 2. An interview on 5/15/23 at 10:04 am with the Laboratory Director revealed the laboratory had not employed a qualified clinical consultant.