Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	17D2133403	03/25/2024
Name of Provider or Supplier	**Street Address, City, State**	
4m Healthcare, Llc	15110 Glenwood, Overland Park, KS	

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	A routine recertification survey was conducted March 14 to 25, 2024. It was determined that Immediate Jeopardy existed for the following condition level deficiencies: 42 C.F.R. 493.1250 Condition: Analytic Systems 42 C.F.R. 493.1290 Condition: Postanalytic Systems 42 C.F.R. 493.1409 Condition: Laboratories Performing Moderate Complexity Testing: Technical Consultant 42 C.F.R. 493.1341 Condition: Laboratories Performing High Complexity Testing: Laboratory Director 42 C.F.R. 493.1361 Condition: Laboratories Performing High Complexity Testing: Technical Supervisor On March 15, 2024, the laboratory ceased testing; therefore, Immediate Jeopardy was removed.
D2005	ENROLLMENT CFR(s): 493.801(a)(4) Authorize the proficiency testing program to release to HHS all data required to-- (i) Determine the laboratory's compliance with this subpart; and (ii) Make PT results available to the public as required in section 353(f)(3)(F) of the Public Health Service Act. This STANDARD is not met as evidenced by: Based on the review of the CMS Casper report 96, Form CMS-116 application test lists, and interview with the Director of Quality Assurance (DQA), the laboratory failed to authorize the College of American Pathologists (CAP) proficiency testing (PT) program to release to HHS all data required to determine the laboratory's compliance for PT testing and evaluation. Findings: 1. The review of the CMS Casper report 96 for this laboratory revealed no data was available for PT scores. 2. Interview with the DQA on 3/14/24 confirmed, the laboratory failed to authorize the CAP PT program to release to HHS all data required to determine the laboratory's compliance for PT testing and evaluation.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES

	CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on the review of the Form CMS-209, lack of documentation, and interview with the Director of Quality Assurance (DQA), the laboratory failed to assess the competency of the clinical consultant (CC) for 2022, 2023, and to date 2024. Findings: 1. Review of the Form CMS-209 revealed one person designated as the CC. 2. The surveyor requested a competency assessment for the CC. No competency documentation for the CC was available at the time of survey for 2022, 2023, and to date 2024. 3. Interview with DQA 3/22/24 at 12:35 p.m. confirmed, the laboratory failed to assess the competency for the position of CC for 2022, 2023, and to date 2024.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on a review of proficiency testing (PT) records from the College of American Pathologists (CAP), lack of evaluation documentation, and interview with the Director of Quality Assurance (DQA), the laboratory failed to evaluate unacceptable proficiency testing results for one of three Hematology testing events from 9/18/23 to 3/6/24. Findings: 1. Review of FH 13-C 2023 Hematology Auto Differentials revealed six test samples received a grade of unacceptable. Evaluation and corrective action (CA) were documented for FH 13-11-15. No evaluation or CA was provided on BCP-23 Blood Cell ID for a grade of unacceptable. The laboratory director (LD) signed the evaluation on 12/13/23. 2. Phone interview with the DQA on 3/21/24 at 8:55 a.m. confirmed, the laboratory failed to evaluate unacceptable proficiency testing results for one of three Hematology testing events from 9/18/23 to 3/6/24.
D5213	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1) The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program. This STANDARD is not met as evidenced by: Based on a review of College of American Pathologists (CAP) proficiency testing (PT) records for 2023, 2024, and interview with the Director of Quality Assurance (DQA), the laboratory failed to evaluate its proficiency testing results for Hematology for three of three events that were not scored by the PT program. Findings: Review of the CAP PT records for three of three Hematology test events revealed: 1. FH13-C 2023: 10 of 15 samples were not graded by the PT program: The LD signed the

	evaluation on 12/13/23. a. FH13-11-15 were not graded for nRBC/100 WBC, nRBC, Absolute. No evaluation documentation was available for review. b. BCP-26-30 were not graded for Blood Cell ID. No evaluation documentation was provided at the time of survey. 2. BCP-A 2024 Blood Cell ID: Five of ten samples were not graded by the PT program. The LD signed the evaluation on 3/13/24. a. BCP-06-10 Blood Cell ID were not graded by the PT program. No evaluation documentation was available for review. 3. Phone interview with the DQA on 3/21/24 .at 8:55 a.m. confirmed, the laboratory failed to evaluate its proficiency testing results for Hematology for three of three events that were not scored by the PT program.
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 procedures without required information, patient testing performed prior to the establishment of performance verification, and lack of comparison studies for test performed on different instrumentation, the laboratory failed to have procedures that included specimen requirements, reportable range (AMR) of test results, , verified reference ranges, and instruction for when test system is not available (refer to D5401); failed to have verification studies to include accuracy determination, and reference ranges as determined by the laboratory (refer to D5421), failed to have 6 month calibration verification studies as required for the Beckman Coulter 690T hematology analyzer (refer to D5439), and failed to have comparison studies for testing performed on two of two 4500 MD HPLC text systems for toxicology, and three of three Thermo Scientific King Fisher Flex instruments for microbiology (refer to D5775).
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 upon a review of the laboratory procedures, interview with the testing personnel (TP) #2, and Form CMS-116 test volumes, the laboratory failed to have written procedures for specimen requirements: collection, labeling, storage, preservation, transportation, criteria for acceptability and rejection, reportable range as verified by the laboratory, patient reference ranges (normal ranges) as determined by the laboratory; system for entering results in the patient record; and course of action when the testing system becomes inoperable for all performed non-waived assays in routine chemistry, endocrinology, and hematology. Findings: 1. Procedures were

	requested for review. Review of the procedures for the Beckman Coulter (BC) Dxl 600 immunoassay analyzer, BC DxH 690T hematology analyzer and BC DxC 700 AU routine analyzer revealed these three procedures did not include specimen requirements for collection, labeling, storage, preservation, transportation, criteria for acceptability and rejection, reportable range as verified by the laboratory, patient reference ranges (normal ranges) as determined by the laboratory, system for entering results in the patient record and course of action when the testing system becomes inoperable. 2. The Form CMS-116 application lists 17,923 patient results are reported annually in routine chemistry, endocrinology, and hematology. 3. Interview with the TP#2 on 3/14/24 at 2:45 p.m. confirmed, the laboratory failed to have available written procedures for specimen requirements: collection, labeling, storage, preservation, transportation, criteria for acceptability and rejection, reportable range as verified by the laboratory, patient reference ranges (normal ranges) as determined by the laboratory; system for entering results in the patient record; and course of action when the testing system becomes inoperable for all performed non-waived assays in routine chemistry, endocrinology, and hematology.
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 the review of performance verification documentation for the BC Dxl 600 immunoassay analyzer, BC DxH 690T hematology analyzer and BC DxC 700 AU routine analyzer, Form CMS-116, and interview with TP #2, the laboratory failed to verify the accuracy and reference intervals (normal values) were appropriate for the laboratory's patient population for all performed non-waived assays in routine chemistry, endocrinology, and hematology prior to reporting patient results. Findings: 1. Review of the performance verification documentation the BC Dxl 600 immunoassay analyzer, BC DxH 690T hematology analyzer and BC DxC 700 AU routine analyzer revealed no documentation to verify the accuracy and reference intervals (normal values) were appropriate for the laboratory's patient population for all performed non-waived assays in routine chemistry, endocrinology, and hematology. Patient testing began on 6/29/23 on three of three analyzers. 2. The laboratory director (LD) signed the verification studies on 5/23/23 for the BC Dxl 600, signed on 5/22/23 for the BC DxH 690T, and signed on 5/10/23 for the BC DxC 700 AU. 3. Review of the Form CMS-116 non-waived test lists revealed 17,923 patient results were reported annually in routine chemistry, endocrinology and hematology. 4. Interview with TP #2 on 3/14/24 at 2:40 p.m. confirmed, the laboratory failed to verify the accuracy and reference intervals (normal values) were appropriate for the laboratory's patient population for all performed non-waived assays in routine chemistry, endocrinology, and hematology prior to reporting patient results.
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 the review of calibration verification records for the BC DxH 690T, quality assurance (QA) reports from BC for July 23, October 23, November 23, and interview with TP #2 revealed that the laboratory failed to perform calibration verification once every six months or as needed when control materials showed a shift in red blood cell (RBC) values. Findings: 1. Review of the calibration verification records for the BC DxH 690T hematology analyzer showed the initial linearity study performed on 1/11 /23 as part of the instrument verification process and 11/15/23 as part of the routine calibration process. 2. Review of the QA reports for the BC DxH 690T revealed a positive shift on RBC QC values for 7/13/23 to 7/31/23, 8/1823 to 9/28/23, and 10/9 /23-11/2/23. 3. Review of the calibration performed on 11/15/23 revealed the RBC required a calibration factor change to correct the instrument's RBC parameters. 4. Interview with TP #2 on 3/20/24 at 10:30 a.m. confirmed, the laboratory failed to perform calibration verification once every six months or as needed when control materials showed a shift in red blood cell (RBC) values.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on an observation of the laboratory's test systems, lack of comparison study documents, Form CMS-116 test , and interview with technical supervisor (TS) #1, the laboratory failed to perform comparison studies in toxicology and microbiology in

	2023 and to date 2024. Findings: 1. Observation of the laboratory showed toxicology and microbiology testing was performed on more than one instrument: a. Toxicology testing was performed on two 4500 MD HPLC test systems. b. Microbiology testing included a component of testing performed on three of three Thermo scientific King Fisher Flex instruments. 2. No documentation of twice yearly for instrument comparison studies was provided at the time of survey for toxicology and microbiology testing. 3. The Form CMS-116 showed annual test volumes for microbiology was 101,398, and for toxicology was 1,121,294. 4. Interview with TS #1 on 3/15/24 at 10:45 a.m. confirmed, the laboratory failed to perform comparison studies in toxicology and microbiology in 2023 and to date 2024.
D5800	POSTANALYTIC SYSTEMS CFR(s): 493.1290 Each laboratory that performs nonwaived testing must meet the applicable postanalytic systems requirements in 493.1291 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 postanalytic systems and correct identified problems as specified in 493. 1299 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on the lack of postanalytic procedures, lack of documented postanalytic processes, test reports with missing results and verified normal ranges, the laboratory failed to monitor and evaluate overall quality of the post analytic system and correct problems identified in testing performed for each specialty and subspecialty. (Refer to D5805, D5807, D5891, D5893)
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on the review of patient test reports, missing test results, lack of a revised report and interview with the Director of Quality Assurance (DQA), the laboratory failed to include 11 of 21 test results on a patient test report. Findings: 1. Review of the final patient test report from 10/4/23 revealed the following test results were not included on the patient report: red blood cell (RBC) count, hemoglobin (HGB), erythrocyte mean corpusclar volume (MCV), erythrocyte mean corpusclar hemoglobin concentration (MCHC), platelets (PLT), lymphocytes (Lymph) percent (%), eosinophil (EOS) %, Lymph absolute (Abs), Monocyte (Mono) Abs, Basophil

	(Baso) Abs, and nucleated red blood cell (nRBC) Abs. 2. Interview with the DQA 3/22 /24 at 3:25 p.m. confirmed, the laboratory failed to include 11 of 21 test results on a patient test report.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on the review of verification studies for normal values for the DxC 700 AU, the DxH 690T and the DxC 600, patient test reports, patient test volumes, and interview, the laboratory failed to have available, normal values as determined by the laboratory. Findings: 1. Review of the verification studies for the DxC 700 AU, the DxH 690T and the DxC 600 revealed the laboratory had not performed normal range studies for all analytes performed on these analyzers (refer to D5421). 2. A sample review of patient reports included normal ranges for complete blood cell counts (CBC) performed on DxH 690T, comprehensive metabolic panel (CMP) performed on the DxC 700 AU, and thyroid stimulating hormone (TSH) performed on DxC 600. 3. The laboratory revealed 17, 923 patient reports were reported without verified normal ranges. 4. Interview with the Director of Quality Assurance (DQA) on 3/22/24 at 3:25 p.m. confirmed, the laboratory failed to have available normal values as determined by the laboratory.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based upon the lack of procedures, test reports with manual differential values and CBC values that did not correlate, and interview with Director of Quality Assurance (DQA), the laboratory failed to have written policies and procedures for an ongoing process to monitor, assess, and correct problems in the postanalytic system. Findings: 1. Review of patient reports with missing test results and reports with manual differential values and CBC values showed the reports did not correlate. 2. No postanalytic system procedure to assess and correct problems was available for review. 3. Interview with the DQA on 3/22/24 at 3:25 p.m. confirmed, the laboratory failed to have written policies and procedures for an ongoing process to monitor, assess, and correct problems in the postanalytical system.
D5893	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(b)(c) (b) The postanalytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of

	postanalytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all postanalytic systems quality assessment activities. This STANDARD is not met as evidenced by: Based on the lack of postanalytic review documentation, lack of corrective action (CA) documentation, and interview with the Director of Quality Assurance (DQA) the laboratory failed to document postanalytic quality assessment. Findings: 1. The surveyor requested documentation of postanalytical quality assessment activities. No postanalytic quality assessment documentation was available at the time of survey. 2. Interview with the DQA on 3/22/24 at 3:25 p.m. confirmed, the laboratory failed to document postanalytic quality assessment.
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: The laboratory failed to have a qualified technical consultant (TC) to oversee all moderate complexity testing in routine chemistry, endocrinology and hematology. Refer to D6034, D6036, and D6046
D6034	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 The laboratory must employ one or more individuals who are qualified by education and either training or experience to provide technical consultation for each of the specialties and subspecialties of service in which the laboratory performs moderate complexity tests or procedures. The director of a laboratory performing moderate complexity testing may function as the technical consultant provided he or she meets the qualifications specified in this section. This STANDARD is not met as evidenced by: Based on the review of the Form CMS-209, personnel qualifications, and interview with the Director of Quality Assurance (DQA), the laboratory failed to have an individual who qualified to perform the duties and responsibilities of the technical consultant (TC) for routine chemistry, endocrinology, and hematology. Findings: 1. Review of the Form CMS-209 revealed one person listed at the TC for routine chemistry, endocrinology, and hematology. 2. Review of personal qualifications revealed the laboratory failed to have a qualified individual for the position of TC. 2. Interview with the DQA on 3/14/24 at 1:05 p.m. confirmed, the laboratory failed to have an individual who qualified to perform the duties and responsibilities of the technical consultant (TC) for routine chemistry, endocrinology, and hematology..
D6036	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413 The technical consultant is responsible for the technical and scientific oversight of the

	laboratory. This STANDARD is not met as evidenced by: Based on the review of the Form CMS-209, maintenance logs, quality control (QC) logs, six month calibration verification data, temperature logs, for the DxC 700 AU, the DxH 690T and the DxC 600 analyzers, and interview with the Director of Quality Assurance (DQA) , the TC failed to provide technical oversight for moderate complexity testing in routine chemistry, endocrinology and hematology. Findings: 1. Review of the Form CMS-209 showed no qualified individual for the position of TC. 2. Review of maintenance logs, quality control (QC) logs, six month calibration verification data, and temperature logs for the DxC 700 AU, the DxH 690T and the DxC 600 analyzers revealed all documents were reviewed by TP #2 who does not qualify as a TC. 3. Interview with DQA on 3/14/24 at 12:50 p.m. confirmed, the TC failed to provide technical oversight for moderate complexity testing in routine chemistry, endocrinology and hematology.
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 the review of competencies for two of two moderate complexity TP, lack of documentation of a qualified TC and interview with the Director of Quality Assurance (DQA) , a qualified TC failed to evaluate competency for two of two moderate complexity TP in routine chemistry, endocrinology and hematology. Findings: 1. Review of the competencies for TP #2 and TP #3 revealed no documentation from a qualified TC for routine chemistry, endocrinology or hematology was present was present on both TP#2 and TP #3. 2. Interview with the DQA 3/14/24 at 1:05 p.m. confirmed, a qualified TC failed to evaluate competency for two of two moderate complexity TP in routine chemistry, endocrinology, and hematology.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: The laboratory director (LD) fails to provide overall management and direction in accordance with 493.1445. Refer to D6086, D6101, D6102 and D6107.
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) The laboratory director must ensure that 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 the review of instrument verification records for the DxC 700 AU, the DxH 690T and the DxC 600 analyzers and interview with the DQA, the laboratory director failed to ensure the establishment of acceptable levels of analytical performance. Cross reference to D5421.
D6101	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(11) The laboratory director must 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: Based on the review of the Form CMS-209 personnel form, lack of qualified individuals for the TC in routine chemistry, endocrinology and hematology, lack of qualified individuals for the TS in hematology, and interview with the DQA, the LD failed to employ qualified personnel for the TC in routine chemistry, endocrinology and hematology and TS in hematology. Findings: 1. Review of the Form CMS-209 revealed: a. One TC for chemistry and hematology who failed to qualify for the position. b. No TS for hematology was on the document. c. The LD signed the Form CMS-209 on 3/5/24. 2. Interview with the DQA on 3/14/24 at 12:50 p.m. confirmed, the LD failed to employ qualified personnel for the TC in routine chemistry, endocrinology and hematology and TS in hematology. .
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must 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 a review of available training records, and interview with the DQA, the laboratory director (LD) failed to ensure that two of two TP receive the appropriate training for moderate complexity testing in routine chemistry and endocrinology, and for both moderate and high complexity testing in hematology prior to testing patient specimens. Findings: 1. No training records were available for TP #2 and TP #3 that included: a. Documentation by a qualified TC for moderate complexity testing in routine chemistry, endocrinology and hematology. b. Documentation by a qualifed TS for high complexity testing in hematology. 2. Competencies for both TP #2 and TP #3 were signed by the LD on 3/14/24. The LD does not qualify as a TC for routine chemistry, endocrinology and hematology or as a TS for hematology. 3. Interview with the DQA on 3/14/24 at 1:05 p.m. confirmed, the LD failed to ensure that two of two TP received the appropriate training for moderate complexity testing in routine

	chemistry and, endocrinology, and for both moderate and high complexity testing in hematology prior to testing patient specimens.
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as 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 result reporting and whether supervisory or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based upon a lack of written responsibilities and duties delegated, and interview with the DQA, the LD failed to specify in writing the written responsibilities and duties of each consultant and supervisor as well as each person performing patient testing. Findings: 1. The surveyor requested documentation of written responsibilities and duties delegated to the clinical consultant, technical consultant, technical supervisor, general supervisor, and testing personnel. No documentation was provided at the time of survey. 2. Interview with the DQA on 3/14/24 at 1:30 p.m. confirmed, the LD failed to specify in writing the written responsibilities and duties of each consultant and supervisor as well as each person performing patient testing.
D6108	LABORATORY TECHNICAL SUPERVISOR CFR(s): 493.1447 The laboratory must have a technical supervisor who meets the qualification requirements of 493.1449 of this subpart and provides technical supervision in accordance with 493.1451 of this subpart. This CONDITION is not met as evidenced by: The laboratory failed to have an individual who qualified or performed the duties and responsibilities of the technical supervisor (TS) for hematology. Refer to D6109 and D6127.
D6109	TECHNICAL SUPERVISOR QUALIFICATIONS CFR(s): 493.1449 The laboratory must employ one or more individuals who are qualified by education and either training or experience to provide technical supervision for each of the specialties and subspecialties of service in which the laboratory performs high complexity tests or procedures. The director of a laboratory performing high complexity testing may function as the technical supervisor provided he or she meets the qualifications specified in this section. This STANDARD is not met as evidenced by: Based on the review of the Form CMS-209, Form CMS-116, test reports for manual differentials, personnel documentaion, and interview with the Director of Quality

	Assurance (DQA), the laboratory failed to have a qualified person for the position of technical supervisor (TS) for the specialty of hematology. Findings: 1. Review of the Form CMS-209 revealed no person was listed a TS for the specialty of hematology. 2. Review of the Form CMS-116 showed the laboratory reported manual complete blood cell differentials. 3. Review of test reports for manual differentials included abnormal results that would classify this test as high complexity. 4. Interview with the DQA 3/14 /24 at 10:05 a.m. confirmed, the laboratory failed to have a qualified person as TS for the specialty of hematology.
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on the review of the semiannual competency documentation for two of two testing personnel (TP) for hematology manual differentials, interview with the Director of Quality Assurance (DQA), the TS failed to determine competency on two of two TP performing high complexity hematology testing. Findings: 1. No semiannual competency documentation performed by a qualified TS was available for review for two of two TP for manual differentials in the specialty of hematology. 2. Interview with the DQA on 3/14/24 at 1:05 p.m. confirmed, the TS failed to determine competency on two of two TP performing high complexity hematology testing.