Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	32D1076170	01/13/2021
Name of Provider or Supplier	**Street Address, City, State**	
Amc Laboratory	1600 West 21st Street Suite B, Clovis, NM	

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	During a recertification survey completed on 01/13/2021 for 42 CFR part 493 Laboratory Requirements, the facility was found out of compliance with the following conditions: 42 CFR Part 493.1250 Analytic Systems 42 CFR Part 493.1403 Laboratory Director, Moderate Complexity 42 CFR Part 493.1441 Laboratory Director, High Complexity
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on review of quality control records, General Quality Assessment Policy, plate detail reports printed with every run and with every tray/plate, email confirmation, interviews with laboratory staff, the laboratory failed to maintain copies of the hematology quality control package inserts (manufacturer instructions) for the quality control materials used for CBC (Complete Blood Count) testing performed on the Abbott Emerald Analyzer and Quality assessment records for the TheraTest system. Findings are: A. Review of the quality control records revealed the laboratory had the instructions for the quality control material used for the new hematology analyzer, the Sysmex XN-330. According to the validation records, the new analyzer was put into use on 10/29/2020. There were no quality control instructions for the previous hematology analyzer, the Cell Dyne Emerald. B. During interview on 01/12/2021 at 11:18 am, the Technical Consultant stated the laboratory staff were requesting copies of the quality control package inserts for 2020 from the manufacturer of the Cell Dyne quality control materials because they could not find the originals. 43577 C. Review of the General Quality Assessment Policy revealed the lab failed to follow a written policy in regards to record retention of Quality Control data. 1. Written policy states

	that quality control data and patient test results (including instrument printouts) are to be kept at least 2 years. 2. Quality assessment records are to be kept at least 2 years. D. Review of the two plate detail reports from runs, for EL-RF/3 (test used for the detection and measurement of rheumatoid factor in human serum and used as an aid to the diagnosis of Rheumatoid Arthritis) assay, performed on 7/21/2020 and 9/23 /2020 and printed from the TERIS 6.1 Software (TheraTest ELISA Reader Information System, version 6.1) revealed that the QC form (Checklist) for subsequent plates, in the same run, had not been filled out. The QC form must be completed to document that QC was acceptable for the entire run, and must be signed and dated by qualified testing person. These QC forms were not retained and were shredded by the laboratory Technical Supervisor. The Technical Supervisor also serves as the General Supervisor and Testing Person. E. During interview on 01/12 /2021 at 2:52 pm, via speaker phone during the survey in the presence of the Technical Supervisor, the TheraTest Technical Specialist stated that a single and separate QC form (Checklist) is generated from the TERIS Software for every 96 well plate that is read by the Biotek ElX800 Plate Reader. He stated that these QC forms (checklist) must be filled out for every plate read and the performing tech is to accept or reject the run, based on the values, which should fall within a range listed on the data sheets provided with each test kit/lot number. When asked if the QC analysis process was in the procedure and if it was being trained in the field, the TheraTest Technical Specialist stated, "Yes it is." During the same interview, the Technical Supervisor was asked if she was assessing the QC in the same manner as stated by the Technical Specialist, for every single, individual plate. The Technical Supervisor confirmed that she only keeps the first QC form (Checklist) for the first plate and not the subsequent QC forms that print if the run consists of more than one plate. She also stated that she was not trained to fill out, accepting or rejecting, each subsequent QC form for each of the plates on the run. F. Email from the Technical Supervisor sent 01 /25/21 at 7:53 pm confirmed that she is shredding all the subsequent QC forms when the run consists of more than one 96 well plate. Her response in the email read "When I print off the QC/Calibration page this is the only page I keep a hard copy of and I shred the rest because everything is saved on 3 different locations: my computer, jump drive, and TheraTest." She also wrote that she only keeps the hard copy of the plate details and the one QC/Calibration page for every run and that she can easily reprint the subsequent QC pages if needed.
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 personnel competency policies, CMS (Centers for Medicare & Medicaid Services) Personnel Report Form 209, Designation of Duties, personnel records and interview with the Technical Consultant, the laboratory failed to establish and follow a policy for evaluating the competency of the Technical Consultant, Technical Supervisor and General Supervisor. Findings are: A. Review of the personnel competency policy signed by the Laboratory Director on 09/17/2018 revealed no process for evaluating the competency of the Technical Consultant, Technical Supervisor and General Supervisor by the Laboratory Director. B. Review of the CMS Personnel Report Form 209, dated 01/08/2021, indicated the Technical

	Supervisor was also the laboratory's General Supervisor and the only high complexity testing person. C. Review of the Designation of Duties, signed by the Laboratory Director on 08/15/18, revealed no distinction between the responsibilities of the General Supervisor and the Technical Consultant by the Laboratory Director. D. Review of personnel files revealed no documentation of evaluations for the responsibilities assigned to the Technical Consultant, the Technical Supervisor or General Supervisor. F. During interview on the morning of 01/13/2021, the Technical Consultant confirmed the Laboratory Director did not perform a competency evaluation regarding her responsibilities as a Technical Consultant.
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 observation, review of the Quality Assessment/Assurance Policies, plate detail test reports (a map that shows the location of patient samples, quality control materials, calibrators on the 96-well plate), Quality Control records, QA Manual for Qualigen FastPack System, the Qualigen FastPack TSH (Thyroid Stimulating Hormone) Method Verification Kit documentation, and the Risk Assessment and Quality Control Plan, and interview with the Technical Supervisor, the laboratory failed to meet the condition of Analytic Systems. The laboratory reported performing 960 TSH tests, 1020 ANA (Antinuclear Antibody-test looks for antinuclear antibodies in your blood), 1020 Anti-CCP (cyclic citrullinated peptide antibodies- are a type of antibody called autoantibodies), 1020 RF (Rheumatoid Factor), 1020 Anti-TPO (Thyroid peroxidase antibody), 1020 Anti-thyroglobulin, 1060 TB (Tuberculosis Bacillus) tests in a 12 month period. Findings are: A. The laboratory failed to perform and document the review and approval of all new QC values/material of each new lot prior to use. See D5469 B. The lab failed to label the newly, received testing kits with pertinent information required for proper use, such as true expiration dates and open /in use dates used to retrieve Quality Control results when necessary for troubleshooting purposes. See D5415 C. The laboratory failed to perform and document the Calibration verification every 6 months, as required by the Manufacturer. See D5437 D. The laboratory failed to have an effective quality assurance policy. See D5793
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 direct observation of the laboratory testing area, refrigerator, and storage areas, the laboratory failed to label the laboratory reagents and kits with the received date, reagent expiration date after preparation, and the revised open reagent expiration dates. Findings are: A. During observation on 1/12/2021 at 10:00 am, the surveyor noticed no "receive" dates or "expiration" dates on the outside of the kits or on the opened reagent bottles inside the following kits. 1. A TB Gold Test Kit by Qiagen (used for Tuberculosis Bacillus testing) found on the laboratory desk with no indication of when it had been received in the laboratory or when it was opened and placed into use. Kit Lot# 56603267, Exp date: 10/23/2022. 2. El-ANA Profiles: ANA /9 kit by TheraTest (used for Anti-Nuclear Antibody testing) was found in the refrigerator with no indication of when it had been received in the laboratory or when it was opened and placed into use. Kit Lot# 09204588, Exp date: 06/17/2021.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on review of QC (Quality Control) records, QA (Quality Assessment) Manual for Qualigen FastPack System, the Qualigen FastPack TSH (Thyroid Stimulating Hormone) Method Verification Kit documentation, and the Risk Assessment and Quality Control Plan, and interview with the Technical Consultant, the laboratory failed to perform and document the calibration verification every 6 months, as required by the manufacturer. Findings are: A. Review of the Quality Control records revealed that the laboratory failed to perform and document the method verification for 2019 and 2020. The last documented performance was 01/10/2018. B. Review of the QA Manual for Qualigen FastPack TSH System indicated that the manufacturer required that the Calibration Verification be performed once every six months. 1. Section labeled "Method Validation", on page 16-3, indicated the following: "Important Note: Calibration Verification (verifying the reportable ranges-Step 1) is performed once every six months. The accuracy and precision portion of method validation (Step 2) is only performed once per analyzer." C. Review of the Qualigen FastPack TSH Method Verification Kit documentation also indicated that the calibration verification and the verification of the reportable range must be performed every six months. 1. TSH Method Verification Kit documentation states "Calibration verification occurs through the testing of three of more levels of calibration materials that include a low, mid, and high value at least every six months. Kit includes materials to meet the requirements for calibration verification and verification of the reportable range." D. Review of the Risk Assessment and Quality Control Plan signed by the Laboratory Director on 08/26/2020, revealed the laboratory failed to follow their written Individualized Quality Control Plan for the calibration verification

	process for the laboratory. 1. The section titled "Calibration Verification" on page 5, states that the calibration verification is to be performed every 6 months. E. During interview on 01/13/2021 at 10:30 am, the Technical Consultant was asked about the missing calibration verification documentation for 2019 and 2020 for the Qualigen FastPack TSH System. She stated that CLIA (Clinical Laboratory Improvement Amendments of 1988) no longer required that the calibration verification be performed on the Qualigen. The laboratory failed to provide documentation from the manufacturer stating that the calibration verification did not have to be performed every six months.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on the review of the General Quality Assessment Policy, the plate detail reports (a map that shows the location of patient samples, quality control materials, calibrators on the 96-well plate) and the corresponding Quality Control (QC) forms (checklist), and the interview with the Technical Supervisor, the laboratory failed to perform and document the review and approval of all new QC values/material of each new lot prior to use. Findings are: A. Review of the General Quality Assessment Policy revealed the laboratory is not following written policy in regards to performing QC (quality control) on new shipments and/or lot numbers of new kits received by the laboratory. 1. Section titled "Control Procedures" on page 11 of the General Quality Assessment Policy states: "[Name of Laboratory] Laboratory uses only FDA-cleared test kits and relies on the manufacturer for the consistency of the test kit. However, as a calibration verification, whenever a new lot number for a particular kit is purchased, the Positive and Negative Controls or the 2 levels of Controls from the previous kit (kept refrigerated, with added preservative, and stable for 1 year) are tested on the first run of the new kit, and the Unit results are compared to the expected values (see individual tests Procedure Manuals, Binder #1) for those Controls. The plate details and expected values are placed in Binder #4 (Internal Controls Data)." B. Plate detail reports revealed incomplete identification of new kit lot numbers when performing Quality Control (QC) on new shipments or new lot numbers received in the laboratory. This failure resulted in the Technical Supervisor's inability to show lot-to-lot QC documentation for each new lot or shipment received prior to testing patients. 1. The Technical Supervisor was asked to produce the documentation of the QC performed on the current lot of the EL-RF/3 (test used for the detection and measurement of rheumatoid factor in human serum and used as an aid to the diagnosis of Rheumatoid Arthritis), Lot #03204263. A plate detail report from 09/23/2020 was

	presented and reviewed. The lot number of the current EL-RF/3 kit did not appear anywhere on the plate detail printout. The Technical Supervisor was asked to identify the well/plate location of the new Lot number QC on the plate detail printout. She identified the lot number as "G1" and "G2" on the plate detail report. The QC form (checklist) attached to the detail report, was filled out, reviewed, and marked as "Accept Run". The QC form had no indication of when the current lot number was received, QC performed, and approved for use or that a lot-to-lot QC assessment had been performed. C. During interview on 01/12/2021 at 2:52 pm, via speaker phone during the survey in the presence of the Technical Supervisor, the TheraTest Technical Specialist stated that a single and separate QC form (Checklist) is generated from the TERIS Software (used to analyze and produce the test results) for every 96 well plate that is read by the Biotek ElX800 Plate Reader. He stated that these QC forms (checklist) must be filled out for every plate read and the performing tech is to accept or reject the run, based on the values, which should fall within a range listed on the data sheets provided with each test kit/lot number. When asked if the QC analysis process was in the procedure and if it was being trained in the field, the TheraTest Technical Specialist stated, "Yes it is." During the same interview, the Technical Supervisor was asked if she was assessing the QC in the same manner as stated by the Technical Specialist, for every single, individual plate. The Technical Supervisor confirmed that she only keeps the first QC form (Checklist) for the first plate and not the subsequent QC forms that print if the run consists of more than one plate. She also stated that she was not trained to fill out, accepting or rejecting, each subsequent QC form for each of the plates on the run.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic 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 analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on the review of the Quality Assessment/Assurance Policies, Quality Assurance Reviews, the plate detail test reports (a map that shows the location of patient samples, quality control materials, calibrators on the 96-well plate) and the corresponding Quality Control (QC) forms (checklist), QC (Quality Control) records, QA (Quality Assessment) Manual for Qualigen FastPack System, the Qualigen FastPack TSH (Thyroid Stimulating Hormone) Method Verification Kit instructions, and the Risk Assessment and Quality Control Plan, and interviews with laboratory staff, the laboratory failed to have an effective quality assurance policy. The laboratory reported performing 960 TSH tests, 1020 ANA (Antinuclear Antibody-test looks for antinuclear antibodies in your blood), 1020 Anti-CCP (cyclic citrullinated peptide antibodies- are a type of antibody called autoantibodies), 1020 RF (Rheumatoid Factor), 1020 Anti-TPO (Thyroid peroxidase antibody), 1020 Anti-thyroglobulin, 1060 TB (Tuberculosis Bacillus) tests in a 12 month period. Findings are: A. The laboratory failed to perform and document the review and approval of all new Quality Control materials of each new lot prior to use. D5469 B. The laboratory failed to perform and document the calibration verification every 6 months, as required by the manufacturer of the Qualigen FastPack test system used for TSH (Thyroid Stimulating Hormone) testing. See D5437 C. Review of the "Quality

	Assurance Reviews" dated 03/19/2020 for February 2020 revealed no documentation of the test systems reviewed, problems identified or corrective actions taken. D. Review of the Quality Assurance policy dated Sept 2018, Section 2. Quality Control Assessment, revealed no policy for assessing the quality control for CBC (Complete Blood Count tests performed using the Sysmex XN-330 and Cell Dyne Emerald) and TSH.
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 the review of the patient daily testing log, the TSH (Thyroid Stimulating Hormone) test result labels printed from the Qualigen Immunochemistry analyzer, and one (PT-TSH#1) patient electronic record, and interview with Technical Supervisor, the laboratory failed to establish and follow a written policy that outlines the process of verifying that results that are manually entered into the LIS (Laboratory Information System), must be periodically verified for accuracy. The laboratory reported a test volume of 960 tests in a 12-month period. Findings are: A. Review of the daily patient testing log on 01/07/2021 indicated the following: 1. Patient name, date of birth, sex, ordering physician and collection date and time. 2. A "check mark" in each column that indicates which tests need to be run. 3. A column for any comments related to distribution of samples. B. Review of the test result labels printed from the Qualigen instrument (this is called their daily "worklist") revealed that the patient name was hand written on the printed instrument label along with the date of birth, time and the name of the ordering physician. These labels were stuck, and kept date and time order on a plain sheet of paper and kept on a clipboard for easy retrieval. There was no documentation indicating the laboratory had a system to verify the results were entered into the LIS. C. During interview held on 01/13/21 at 11:15 am, the Technical Supervisor stated that all TSH results are manually entered into CareCloud (the electronic LIS system) using the printed test labels from the Qualigen instrument as a worklist. She stated that TP#3 is the the person running the TSH tests and she also does the manual entry into CareCloud. When asked if the laboratory had an existing, written policy to verify that manual results were entered correctly she stated that they did not have such a policy and was not aware one was needed. D. Review of one patient (PT-TSH#1) electronic record revealed no documentation that the laboratory verified the accuracy of the information that was manually entered into the electronic CareCloud, LIS system.
D5813	TEST REPORT CFR(s): 493.1291(g) The laboratory must immediately alert the individual or entity requesting the test and, if applicable, the individual responsible for using the test results when any test result

	indicates an imminently life-threatening condition, or panic or alert values. This STANDARD is not met as evidenced by: Based on the review of two (Pt#1-Pt#2) of two (Pt#1-Pt#2) patient records and interview with Technical Supervisor, the laboratory failed to document the notification of all critical results from the hard copy to the permanent electronic record in CareCloud, the laboratory's LIS (Laboratory Information System). Findings are: A. Review of the electronic patient records and the hard copy test results for two patients (Pt#1 and Pt#2), revealed no documentation of the notification of critical result from the testing personnel to the provider or the authorized individual/entity in the electronic medical records. 1. Pt#1 report was completed on 3/8/2019 and was a repeat test, originally performed on 2/27/2019. The hard copy of the report has the following notations: "Repeat from 2/27/2019. Notified [Provider Name] @ 1341 on 3 /8/2019 and tech initials." There was no documentation of this information in the LIS. 2. Pt#2 report was completed on 3/8/2019 and was a repeat test, originally performed on 2/27/2019. The hard copy of the report has the following notations: " Repeat from 2 /27/2019. Notified [Provider Name] @ 1341 on 3/8/2019 and tech initials." There was no documentation of this information in the LIS. C. During interview on 1/13/2021 at 11:15 am, the Technical Supervisor stated that after a positive TB (Tuberculosis Bacillus), she repeats the test for confirmation and, per protocol, she notifies the doctor and the doctor will call patient to schedule a chest X-ray. She confirmed that all documentation is hand written on the patient laboratory report but not transmitted to the patient electronic record. The Technical Supervisor stated that she doesn't always manually document on the test printout because she personally hands the report to the provider.
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 personnel competency policies, 2020 proficiency test records, CMS (Centers for Medicare & Medicaid Services) Personnel Report Form 209, Designation of Duties, personnel records and interview with the Technical Consultant, and interviews with laboratory staff, the Laboratory Director failed to provide overall management and direction of the laboratory. Findings are: A. The Laboratory Director failed to ensure policies were established and followed for timely review of proficiency test scores and any required corrective actions. See D6018 B. The laboratory failed to establish and follow a policy for evaluating the competency of the Technical Consultant, Technical Supervisor and General Supervisor. See D6032
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on the review of 2020 proficiency test records and interview with the Technical Consultant, the Laboratory Director failed to ensure policies were established and followed for timely review of proficiency test scores and any required corrective actions. Findings are: A. During interview on 01/12/2021 at 10:41 am, the Technical Consultant stated the laboratory had notified her on Sunday, 12/15/2020, that the proficiency results had been received by the laboratory. She further stated that corrective actions had not been performed because the results were received after her visit at the beginning of the month. B. Review of the proficiency test scores for the 3rd event of 2020 revealed the laboratory received failing scores (0% and 20% respectively) for RDW-CV and RDW-SD (Red Blood Cell Distribution Width used to evaluate anemia).
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on the review of personnel competency policies, CMS (Centers for Medicare & Medicaid Services) Personnel Report Form 209, Designation of Duties, personnel records and interview with the Technical Consultant, the laboratory failed to establish and follow a policy for evaluating the competency of the Technical Consultant, Technical Supervisor and General Supervisor. Findings are: A. Review of the personnel competency policy signed by the Laboratory Director on 09/17/2018 revealed no process for evaluating the competency of the Technical Consultant, Technical Supervisor and General by the Laboratory Director. B. Review of the CMS Personnel Report Form 209, dated 01/08/2021, indicated the Technical Supervisor was also the laboratory's General Supervisor. C. Review of the Designation of Duties, signed by the Laboratory Director on 08/15/18, revealed no delegation of responsibilities to a Technical Supervisor by the Laboratory Director nor was there a distinction between the responsibilities of the General Supervisor and the Technical Consultant. See D5209
D6045	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(7) (b) The technical consultant is responsible for-- (b)(7) Identifying training needs and

	assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; This STANDARD is not met as evidenced by: Based on observation, review of quality control records, manufacturers instructions, and interviews with laboratory staff, the Technical Consultant failed to identify the training needs of the primary moderate complexity testing person (TP#2) using observation and record review to assess troubleshooting skills. Findings are: A. During interview on 01/12/2021 at 11:18 am, the Technical Consultant stated the laboratory did not have a troubleshooting or problem log to document quality control issues. The testing person is supposed to call her, use a new vial of control or call technical support. B. Review of an example of troubleshooting (dated 07/24/2020) provided by the Technical Consultant, revealed no documentation of the steps taken by the testing person to resolve the quality control failure. C. During interview on 01 /12/2021 at 2:26 pm, TP#2 stated she didn't know she was supposed to document troubleshooting steps. D. Review of the manufacturer's instructions for XN-L Check Hematology control indicated: "Remove a vial of XN-L CHECK from the refrigerator, and equilibrate to room temperature (15-35 degrees Celsius) for 15 minutes before use." E. During observation on 01/12/2021 at 07:55 am -08:45 am, TP#2 failed to allow the refrigerated quality control materials to sit at room temperature at least 15 minutes before running on the Sysmex XN-330 Hematology Analyzer. 07:55 am TP#2 arrived at the laboratory just after the arrival of the survey team. 07:58 am The quality controls materials were seen on the counter next to the analyzer. 08:01 - 08:05 am TP#2 began vortexing or rolling the vials of quality controls in the palms of her hands. (3 minutes after initial observation) 08:06 - 08:10 am All three (3) levels of controls were run on the analyzer. Level 3 results were unacceptable and repeated. (8 minutes after initial observation) 08:13 am The 2nd run of Level 3 still unacceptable and TP#2 brought out a new vial of control from the refrigerator, calling technical support at the same time. 08:17 am Error message "Out of Cell Pack DCL" required TP#2 to open a new reagent pack. 08:19 am 3rd run of Level 3 still unacceptable. (6 minutes after new vial was removed from the refrigerator) 08:24 am - 08:45 am Technical Support on the phone. Recommended 2 different maintenance procedures to correct the problem. Level 3 acceptable on the 4th run after maintenance was performed. TP#2 did not inform Technical Support about the reagent change. F. During interview on 01/12/2021 at 08:22 am, TP#2 stated the controls were supposed to warm about 10-15 minutes prior to use.
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: Based on direct observation and review of General Quality Assessment (QA) Policy, plate detail reports (a map that shows the location of patient samples, quality control materials/records, calibrators on the 96-well plate), the Quality Control forms (checklist), Personnel competency policies and records, CMS (Centers for Medicare & Medicaid Services) Personnel Report Form 209, Designation of Duties, email

	confirmation, and interviews with laboratory staff, the Laboratory Director failed to provide overall management and direction of the laboratory. Findings are: Review of the Designation of Duties dated 07/22/2019 indicated the Laboratory Director delegated all "High Complexity Technical Supervisor" responsibilities to the current Technical Supervisor. The designated Technical Supervisor failed to ensure the laboratory established and implemented an acceptable quality control program that guarantee quality patient results throughout the entire testing process. See D6079
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on direct observation and review of General Quality Assessment (QA) Policy, plate detail reports (a map that shows the location of patient samples, quality control materials/records, calibrators on the 96-well plate), the Quality Control (QC) forms (checklist), Personnel competency policies and records, CMS (Centers for Medicare & Medicaid Services) Personnel Report Form 209, Designation of Duties, email confirmation, and interviews with laboratory staff, the Laboratory Director failed to ensure the laboratory established and implemented an acceptable quality control program that ensures that the laboratory is producing reliable patient results throughout the entire testing process. Findings are: Review of the Designation of Duties dated 07/22/2019 indicated the Laboratory Director delegated all "High Complexity Technical Supervisor" responsibilities to the current Technical Supervisor. The designated Technical Supervisor failed to ensure: A. The performance and the approval of all Quality Control procedures for all QC for new kits /lots prior to use. See D5469 B. Retention of all Quality assessment records as confirmed by email dated 01/25/21 at 7:53 pm. See D3031(C-F). C. The labeling of all laboratory reagents and kits with the received date, reagent expiration date after preparation, and the revised open reagent expiration dates. See D5415 D. The establishment of a written policy for evaluating the competency of the Technical Supervisor and General Supervisor. See D5209
D6117	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(4) The technical supervisor is responsible for establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results.

	This STANDARD is not met as evidenced by: Based on direct observation and review of General Quality Assessment (QA) Policy, plate detail reports (a map that shows the location of patient samples, quality control materials/records, calibrators on the 96-well plate), the Quality Control (QC) forms (checklist), Personnel competency policies and records, CMS (Centers for Medicare & Medicaid Services) Personnel Report Form 209, Designation of Duties, email confirmation, and interviews with laboratory staff, the Technical Supervisor failed to establish and implement an acceptable quality control program that ensures that the laboratory is producing reliable patient results throughout the entire testing process. Findings are: A. The laboratory failed to follow written procedures for the performance and the approval of all Quality Control procedures for all QC for new kits /lots prior to use. See D5469 B. The laboratory failed to Retain Quality assessment records as confirmed by email dated 01/25/21 at 7:53 pm. See D3031(C-F). C. The laboratory failed to label the laboratory reagents and kits with the received date, reagent expiration date after preparation, and the revised open reagent expiration dates. See D5415 D. The laboratory failed to establish and follow a policy for evaluating the competency of the Technical Supervisor and General Supervisor. See D5209