Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D2113375	07/26/2021
Name of Provider or Supplier	**Street Address, City, State**	
Lindsay York, Md, Llc	1111 Medical Center Blvd N803, Marrero, LA	

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 Recertification Survey was performed at Lindsay York, MD Pediatrics-CLIA # 19D2113375 on July 26, 2021. Lindsay York, MD was found not in compliance with the following CONDITION LEVEL DEFICIENCIES: 42 CFR 493.1215 CONDITION: Hematology 42 CFR 493.1403 CONDITION: Laboratories performing moderate complexity testing; Laboratory Director
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on observation by surveyor, review of the U.S. Food and Drug Administration recall memo, patient test logs, and interview with personnel, the laboratory failed to discontinue use of recalled LeadCare II kits as required for one (1) of (1) patient reviewed. Findings: 1. Observation by surveyor during laboratory tour on July 26, 2021 at 9:40 am revealed the laboratory had one (1) LeadCare II kit, lot # 2013M in use, opened on July 6, 2021. 2. Review of the FDA "Magellan Diagnostics Recalls LeadCare II, LeadCare Plus, and LeadCare Ultra Blood Lead Tests Due to Risk of Falsely Low Results" memo revealed the following recalled kits and customer directives: " LeadCare II: 2013M, 2014M, 2015M, 2016M, 2017M, 2102M, 2103M, 2105M, 2016M, and 2017M. LeadCare Plus and LeadCare Ultra: 2011 MU, 2104MU, and 2108M. Customers: Discontinue use of all test kit lots identified as part of the recall and quarantine remaining inventory. Laboratories should evaluate patient test results that were generated with the impacted lots. Confirm suspect results with an alternative lead testing options, such as those using inductively coupled plasma mass spectrometry or graphite furnace atomic absorption spectroscopy at a high complexity, CLIA-certified, reference laboratory. Promptly complete and return the

	Customer Notification Form in the Urgent Medical Device Recall letter. After the form has been submitted, contact Magellan Technical Support. Be aware, product will be replaced based on availability; replacement product is NOT currently available." 3. In interview on July 26, 2021 at 9:41 pm, the Lead Medical Assistant stated the laboratory received the identified LeadCare II lot on January 28, 2021. The Lead Medical Assistant further stated the laboratory was unaware of the recall of the identified LeadCare II kits. 4. Review of patient logs revealed the laboratory reported one (1) patient utilizing the recalled lot number on July 7, 2021.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, proficiency testing records, and interview with personnel, the laboratory failed to ensure attestation statements were signed by the appropriate personnel as required for three (3) of seven (7) proficiency testing (PT) events reviewed. Findings: 1. Review of the laboratory's "Proficiency Testing" policy revealed " The laboratory director will sign the attestation statement confirming that the PT samples were tested in the same manner as the patient specimens. The laboratory director will attest to the individual performing the test. This should be kept in a binder labeled 'proficiency testing.' " 2. Review of the laboratory's "Attachment 6031 Proficiency Testing" policy revealed "Keep a copy of all records associated with PT testing, including the signed attestation sheet, instrument printouts, the results form submitted to the PT agency, and the graded results report. Retain these records for two years from the PT even date." 3. Review of the laboratory's American Proficiency Institute's (API) PT results for 2019, 2020, and 2021 revealed the laboratory did not ensure attestation statements were signed by personnel as follows: a) 2019 Hematology/Coagulation 2nd Event: Laboratory Director and Testing Personnel b) 2020 Hematology/Coagulation 3rd Event: Laboratory Director and Testing Personnel c) 2021 Hematology/Coagulation 1st Event: Laboratory Director and Testing Personnel 4. In interview on July 26, 2021 at 3:35 pm, the Lead Medical Assistant confirmed the appropriate personnel did not sign the PT attestation statements as required.
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 laboratory policies and procedures, quality control (QC) records, and interview with personnel, the laboratory failed to retain QC records for at least two (2) years as required for the Sysmex XN-330 analyzer for one (1) of three (3) months reviewed. Findings: 1. Review of the laboratory's "Analytic Phase" policies and procedures revealed " Keep all QC records for at least 2 years" 2. Review of the laboratory's Sysmex XN-330 analyzer's QC records for December 2019, September 2020, and June 2021 revealed the laboratory did not retain records for December 2019. 3. In interview on July 26, 2021 at 11:56 am, the Lead Medical Assistant confirmed the laboratory did maintain the identified QC records.
D5024	HEMATOLOGY CFR(s): 493.1215 If the laboratory provides services in the specialty of Hematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1269, and 493. 1281 through 493.1299. This CONDITION is not met as evidenced by: Based on observation by surveyor, record review, and interview with personnel, the laboratory failed to ensure the quality of testing for the specialty of Hematology. Findings: 1. The laboratory failed to document the review of the performance evaluation for four (4) of seven (7) proficiency testing (PT) events reviewed. Refer to D5211. 2. The laboratory failed to perform an assessment for three (3) of seven (7) proficiency testing (PT) events reviewed. Refer to D5221. 3. The laboratory failed to follow established laboratory policies for Complete Blood Count (CBC) flags. Refer to D5401. 4. The laboratory failed to ensure policies and procedures were updated to current practices. Refer D5407. 5. The laboratory failed to ensure reagents did not exceed their expiration date. Refer to D5417. 6. The laboratory failed to have complete performance verification studies for the Sysmex XN-330 analyzer. Refer to D5421. 7. The laboratory failed to ensure maintenance for the Sysmex XN-330 was performed as required for twenty (20) of twenty two (22) months reviewed. Refer to D5429. 8. The laboratory failed to establish the quality control performance prior to use per manufacturer requirements for the Sysmex XN-330. Refer to D5469. 9. The laboratory's quality assessment monitors failed to correct issues identified with the analytic system. Refer to D5793.
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 review of the laboratory's policies, proficiency testing records, and interview with personnel, the laboratory failed to document the review of the performance evaluation for four (4) of seven (7) proficiency testing (PT) events reviewed. Findings: 1. Review of the laboratory's "Evaluation Proficiency Testing Performance" policy revealed "Employees and the laboratory director review and evaluate the results from the proficiency testing. If all results are acceptable, the laboratory director

	will then sign off on the results." 2. Review of the laboratory's American Proficiency Institute (API) proficiency testing (PT) results for 2019, 2020, and 2021 revealed the Laboratory Director did not evaluate the results for the following four (4) PT events: a) 2019 Hematology/Coagulation 2nd Event b) 2019 Hematology/Coagulation 3rd Event c) 2020 Hematology/Coagulation 2nd Event d) 2021 Hematology/Coagulation 1st Event 3. In interview on July 26, 2021 at 3:35 pm, the Lead Medical Assistant confirmed the Laboratory Director did not review/sign the identified results of the identified PT events. .
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, proficiency testing records, and interview with personnel, the laboratory failed to perform an assessment for three (3) of seven (7) proficiency testing (PT) events reviewed. Findings: 1. Review of the laboratory's "Evaluation Proficiency Testing Performance" policy revealed "Employees and the laboratory director review and evaluate the results from the proficiency testing. If all results are acceptable, the laboratory director will then sign off on the results. If any results are unacceptable, we will perform corrective action as required, which may or may not include repeating the proficiency testing. Our corrective action is then reviewed with all employees and the laboratory director. The corrective action is documented and signed off by the laboratory director." 2. Review of the laboratory's 2019, 2020, and 2021 PT results revealed the following "unacceptable" PT results: a) 2019 Hematology/Coagulation 3rd Event: Hemoglobin: Sample HSY-14, score 80% Red Cell Count: Sample HSY-14, score 80% b) 2020 Hematology/Coagulation 1st Event Hemoglobin, score 80% c) 2021 Hematology/Coagulation 1st Event Hematocrit: Sample XE-02, score 80% White Blood Cell Differential: overall score 84 %: (Basophils, Lymphocytes, Monocytes, and Neutrophils ,sample XE-04 scores 80%) 3. In interview on July 26, 2021 at 3:35 pm, the Lead Medical Assistant stated the laboratory did not have additional records for PT other than what was provided. The Lead Medical Assistant confirmed the laboratory did not perform assessments for scores less than 100%.
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: **Repeat deficiency from survey performed on January 22, 2019** Based on observation by surveyor, review of the laboratory's policies, manufacturer's instructions, patient instrument printouts, and interview with personnel, the laboratory failed to follow established laboratory policies for Complete Blood Count (CBC) flags. Findings: 1. Observation by surveyor on July 26, 2021 at 11:03 am, revealed the laboratory utilizes the Sysmex XN-330 for CBC testing. 2. Review of the laboratory's

	policies under "Troubleshooting Flagged Results" section revealed "Follow the manufacturer's instructions for handling codes, flags and messages displayed with patient results, including flagged automated differential reports. If the SYSMEX Coulter's specific troubleshooting advice does not solve the problem, retest the patient sample. Mix the specimen then re-test; if flags do not clear, refer results to provider or Laboratory Director for a decision as to further actions. See attached Document for Flagged Results. Take corrective action as described in the operator's manual. The laboratory is following all instructions in the operators manual. Do not report patient results on values that are flagged and require another method to validate. Indicate to the provider and write that the VALUE IS NOT REPORTABLE." 3. Review of the laboratory's policies under "Reporting Results" section revealed "Note: In rare instances, a transient or partial aperture blockage may not be detected by any of these methods. Therefore, carefully review flagged results and any result that exceeds your patient reference ranges for accuracy by the repeating the test. If the patient test result appears inconsistent with clinically relevant criteria or previous patient test results, confer with the laboratory director to see if the specimen should be sent to an outside laboratory for confirmation." 4. Review of the "Sysmex XN-L Series Flagging Guide" revealed "All analyzer flags, error messages and results must be interpreted together and in consideration of the patient's clinical condition prior to results being reported from the laboratory. Any asterisk (*) next to a parameter indicates these results may be unreliable and should be confirmed according to your laboratory protocol prior to reporting. Protocols for comparison of current results to previous results (delta checking) as well as critical value results are also useful for identifying potentially erroneous results prior to reporting to the clinician." 5. Review of the following random selection of patient reports revealed the laboratory circles the instrument flags and a comment stating "Unconfirmed/Void Specimen will not be used by physician for patient treatment." The patient sample was not retested. The reports have the Testing Personnel and Laboratory Director's initials: May 31, 2021: Patient 14084 Flags: "PLT: *, MPV: *, BASO: *WBC Scattergram. Macrocytosis, Thrombocytopenia, PLT Clumps ? #1: Make smear and scan" July 12, 2021: Patient 13463 Flags: "PLT: *, MPV: *, Anemia, PLT Clumps?" July 21, 2021: Patient 14103 Flags: PLT: *, MPV: * 6. In interview on July 26, 2021 the Lead Medical Assistant confirmed the laboratory circles the instrument flags for the Laboratory Director's review. The Lead Medical Assistant confirmed the laboratory does not retest the patient samples that contain flagged results.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedures and interview with personnel, the laboratory failed to ensure policies and procedures were updated to current practices. Findings: 1. Review of the laboratory's policies and procedures revealed the laboratory did not have current policies/practices for the following: a) "Proficiency Testing" to include the laboratory's current instrumentation (Sysmex) b) "Attachment 6031 Proficiency Testing" to include the laboratory's correct proficiency agency (American Proficiency Institute) 2. In interview on July 26, 2021 at 1:20 pm, the Lead Medical Assistant confirmed the laboratory's policies did not include their current practices.

D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on observation by surveyor and interview with personnel, the laboratory failed to ensure reagents did not exceed their expiration date. Findings: 1. Observation by surveyor during laboratory tour on July 26, 2021 at 11:05 am revealed the following expired reagents: Sysmex WPC Lysercell WPC, Lot # A0006, Expiration date: 2021-04-22, Quantity: two (2) containers 2. In interview on July 26, 2021 at 11:05 am, the Lead Medical Assistant (Testing Personnel) confirmed the identified items were expired.
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 observation by surveyor, review of validation records, test menu, and interview with personnel, the laboratory failed to have complete performance verification studies for the Sysmex XN-330 analyzer. Findings: 1. Observation by surveyor during the laboratory tour on July 26, 2021 at 11:05 am revealed the laboratory utilizes the Sysmex XN-330 analyzer for Complete Blood Count (CBC) testing. 2. In interview on July 26, 2021 at 9:42 am, the Lead Medical Assistant stated the laboratory had renovations in February 2021. In further interview the Lead Medical Assistant stated the laboratory discontinued use of the Medonic analyzer for CBC testing October 30, 2019 and started using the Sysmex. 3. In interview on July 26, 2021 at 3:25 pm, the Laboratory Director stated on July 10, 2021 the Sysmex analyzer was moved to a different location following the laboratory's renovations. 4. Review of the laboratory's "PREANALYTIC POLICIES AND PROCEDURES" under "Verifying Performance Specifications" section revealed the following: " Method Validation Policies: Before a new non-waived test is implemented, this laboratory demonstrates that it can obtain performance specifications comparable to those established by the manufacturer for accuracy, precision, and reportable range through method validation. The laboratory director also verifies the appropriateness of the manufacturer's reference (normal) values for the laboratory's patient population prior to using the analyzer for patient testing. The procedure would be done as specified by SYSMEX Coulter for validation." 5. Review of the laboratory's "New Instruments" and "New CBC instruments" procedures revealed the following: a) "The lead medical assistant will be responsible for identifying and performing the required testing." b) "When a new CBC machine is introduced to the practice, the following

	will be done in the office, prior to patient testing: accuracy, precision, and calibration verification (manufacturer) , reportable range/linearity study (manufacturer), reportable range validation (manufacturer), performance studies (laboratory director), operator variance (laboratory director)" c) " A report will be composed by the laboratory director. The laboratory director will sign off and approve the report for the new instrument. This report will be located in the laboratory policy and procedure manual." 6. Review of the laboratory's policies and procedures revealed the laboratory did not have a procedure regarding instrument verification following the move of an instrument to ensure accuracy of its performance. 7. Review of the laboratory's performance verification studies for the Sysmex XN-330 analyzer revealed the laboratory did not include the following: a) Procedure and Raw data to verify accuracy of the instrument's performance following the instrument's move b) Clinical reference or studies to support the reference range in use c) Laboratory Director's review /approval 8. In interview on July 26, 2021 at 2:15 pm, the Laboratory Director stated the reference ranges came from a clinical reference. The Laboratory Director confirmed the clinical reference was not cited in the laboratory's performance verification studies. 9. In further interview on July 26, 2021 at 3:25 pm, the Laboratory Director stated Sysmex has the laboratory's QC files and checks related to the instrument's move. The Laboratory Director confirmed the laboratory did not maintain records verifying the accuracy of the instrument's performance after the move. 10. Review of the laboratory's test menu revealed the laboratory performs 9,000 CBC tests annually.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on observation by surveyor, review of maintenance logs, policies, and interview with personnel, the laboratory failed to ensure maintenance for the Sysmex XN-330 was performed as required for twenty (20) of twenty two (22) months reviewed. Findings: 1. Observation by surveyor during the laboratory tour on July 26, 2021 at 11:05 am revealed the laboratory utilizes the Sysmex XN-330 analyzer for Complete Blood Count (CBC) testing. 2. In interview on July 26, 2021 at 9:42 am, the Lead Medical Assistant stated the laboratory discontinued use of the Medonic analyzer for CBC testing October 30, 2019 and started using the Sysmex. 3. Review of the laboratory's "Instrument Maintenance" policy revealed " Clean the outside of the instrument with a damp cloth and distilled water to prevent buildup of corrosive deposits. Clean up spills promptly, paying particular attention to the probe wipe housing. When prompted by the instrument, perform maintenance. Use the Maintenance LOG to record all maintenance performed on the SYSMEX XN-330 Automated Hematology Analyzer." 4. Review of Sysmex maintenance logs revealed daily shutdown and weekly cleaning tasks. 5. Review of the laboratory's Sysmex XN-330 analyzer's maintenance records from October 2019 through July 2021 revealed the laboratory did not retain records for the following months: a) 2019: October, November, December b) 2020: no maintenance records (January through December) c) 2021: January, February, March, April, May 6. In interview on July 26, 2021 at 11: 56 am, the Lead Medical Assistant confirmed the laboratory did not have documentation of maintenance for the identified months. The Lead Medical Assistant

	further stated at 11:58 am, she was unsure if the instrument tracked performance of maintenance.
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 observation by surveyor, review of manufacturer requirements, quality control (QC) records, test menu, and interview with personnel, the laboratory failed to establish the quality control performance prior to use per manufacturer requirements for the Sysmex XN-330. Findings: 1. Observation by surveyor during the laboratory tour on July 26, 2021 at 11:05 am revealed the laboratory utilizes the Sysmex XN-330 analyzer for Complete Blood Count (CBC) testing with XN-L CHECK controls. 2. Review of the manufacturer's package insert under the "Performance characteristics and limitations" section revealed "The expected ranges listed on the assay sheet represent estimates of inter-laboratory variation for each parameter. These expected ranges should not be used as QC file limits." 3. Review of the manufacturer's application manual under "Section 2 Quality Control" section revealed " The new lot of commercial control product should be run twice a day for five days. When a minimum of 10 points have accumulated, the target should be auto-set. The established target should be within the range of means on the assay sheet provided with each lot of XN-CHECK or XN-L CHECK." 4. Review of the laboratory's quality control records for the laboratory's current lot of XN-L CHECK (lot number 1184) revealed the laboratory did not have documentation of establishing quality control targets prior to use. 5. In interview on July 26, 2021 at 11:58 am, the Lead Medical Assistant stated the laboratory uses the manufacturer's ranges for QC acceptability. 6. In further interview on July 26, 2021 at 1:58 pm, the Lead Medical Assistant stated for new lots of QC she scans the bar code and puts into use without running several days prior to use. 7. Review of the laboratory's test menu revealed the laboratory performs 9,000 CBC tests annually.
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 observation by surveyor, record review, and interview with personnel, the laboratory's quality assessment monitors failed to correct issues identified with the analytic system. Findings: 1. Review of the laboratory's "Quality Assessment" policy revealed "The QA program comprises the steps taken to assure the overall reliability of our testing system, strating with the proper specimen collection and ending with reporting patient test results. Unlike Quality Contorl, which monitors the test system onely, qA incloces the entire test process including general lab systems (safety, personnel, PT) andlong with the preanlaytic phase (specimen collection and handling), the anlaytic phase (performing the test), and the postanalytic testing phase (reporting patient test results). The Montlhy QA Checklist is our means of ongoing assessment which helps to evaluate how well our policies and procedures are working, and minimizes the possibility of recurrent problems Quality assessment activities are comprehensive and are documented monthly by the technical consultant and reviewed by the Medical Director. The laboratory director oversees the implementation of the QA plan and helps identify and correct problems as they occur." 2. Review of the laboratory's "Monthly Quality Assurance Checklist" revealed the following tasks: a) "The laboratory director was notifies {sic} of any situation that could affect the laboratory's performance of the safety of employees" b) "All new laboratory personnel have read the safety guidelines in this Manual" c) "All new laboratory personnel have been offered the Hepatitis B vaccine" d) "All personnel who perform tests have documented training for these test" e) "All personnel who perform tests have read the procedure manual for those test" f) "Personnel evaluations were performed as necessary" g)"Proficiency tests were handles in the same manner as patient specimens" h) "Proficiency test results were evaluated, failures were investigated, and remedial action was taken" i) "Patient specimens were collected and handled according to our protocol" j) "All blood collectin tubes wee labeled legibily" k) "Specimens were logged correctly on the Laboratory Specimen Log" l) "All lab reports contain correct information" m) "All required temperatures were taken and recorded" n) "All reagents, controls, kits, etc., that exceeded their expiratin date were discarded" o) "Any required instrument maintenance was performed and documented" p) "Any necessary remedial action was performed and documented" q) "All quality control/calibrations were performed and accepted before patient test results were reported" r) "The above information has been reviewedto determine whther errors that occurred could have been prevented by changing our policies or procedures" s) "If you answered 'No' to any of the above, explain the problem and how it was resolved" 3. Observation by surveyor, review of records, and interview with personnel revealed the laboratory did not identify the following issues with the analytic system: a) The laboratory failed to follow established laboratory policies for Complete Blood Count (CBC) flags. Refer to D5401. b) The laboratory failed to ensure policies and procedures were updated to current practices. Refer D5407. c) The laboratory failed to ensure reagents did not exceed their expiration date. Refer to D5417. d) The laboratory failed to have complete performance verification studies for the Sysmex XN-330 analyzer. Refer to D5421. e) The laboratory failed to ensure maintenance for the Sysmex XN-330 was performed as required for twenty (20) of twenty two (22) months reviewed. Refer to D5429. f) The laboratory failed to establish the quality control performance prior to use per manufacturer requirements for the Sysmex XN-330. Refer to D5469.
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 observation by surveyor, record review, and interview with personnel, the Laboratory Director failed to provide overall management and direction for the laboratory. Findings: 1. The Laboratory Director failed to provide overall direction and management to the laboratory. Refer to D6004. 2. The Laboratory Director failed to ensure performance verification studies were complete. Refer to D6013. 3. The Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Refer to D6014. 4. The Laboratory Director failed to ensure all proficiency test report attestation statements were signed by the Laboratory Director and Testing Personnel. Refer to D6018. 5. The Laboratory Director failed to ensure the laboratory performed corrective actions for unacceptable proficiency testing results. Refer to D6019. 6. The Laboratory Director failed to ensure that a quality control program was maintained to assure quality laboratory services were provided. Refer to D6020. 7. The Laboratory Director failed to ensure that a quality assessment (QA) program was maintained to assure the quality of laboratory services provided and to identify failures as they occur. Refer to D6022. 8. The Laboratory Director failed to ensure that the laboratory performed required maintenance. Refer to D6023. 9. The Laboratory Director failed to ensure two (2) of two (2) Testing Personnel had documentation of training for the Sysmex XN-330 analyzer. Refer to D6029. 10. The Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Refer to D6031.
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, 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 observation by surveyor, record review, and interview with personnel, the Laboratory Director failed to provide overall direction and management to the laboratory. Findings: 1. The laboratory failed to discontinue use of recalled LeadCare II kits as required for one (1) of (1) patient reviewed. Refer to D1001. 2. The laboratory failed to retain QC records for at least two (2) years as required for the Sysmex XN-330 analyzer for one (1) of three (3) months reviewed. Refer to D3031.
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 observation by surveyor, record review, and interview with personnel, the Laboratory Director failed to ensure performance verification studies were complete. Refer to D5421.
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(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)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: **Repeat deficiency from survey performed on January 22, 2019** Based on observation by surveyor, record review, and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Findings: 1. The laboratory failed to follow established laboratory policies for Complete Blood Count (CBC) flags. Refer to D5401. 2. The laboratory failed to ensure reagents did not exceed their expiration date. Refer to D5417.
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 record review and interview with personnel, the Laboratory Director failed to ensure all proficiency test report attestation statements were signed by the Laboratory Director and Testing Personnel. Findings: 1. The laboratory failed to ensure attestation statements were signed by the appropriate personnel as required for three (3) of seven (7) proficiency testing (PT) events reviewed. Refer to D2015. 2. The laboratory failed to document the review of the performance evaluation for four (4) of seven (7) proficiency testing (PT) events reviewed. Refer to D5211.

D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure the laboratory performed corrective actions for unacceptable proficiency testing results. Refer to D5221.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on observation by surveyor, record review, and interview with personnel, the Laboratory Director failed to ensure that a quality control program was maintained to assure quality laboratory services were provided. Refer to D5469.
D6022	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on observation by surveyor, record review, and interview with personnel, the Laboratory Director failed to ensure that a quality assessment (QA) program was maintained to assure the quality of laboratory services provided and to identify failures as they occur. Refer to D5793.
D6023	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(6) 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)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system; This STANDARD is not met as evidenced by: Based on observation by surveyor, record review, and interview with personnel, the Laboratory Director failed to ensure that the laboratory performed required maintenance. Refer to D5429.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on review of the laboratory's CMS-209 form (Laboratory Personnel Report), personnel records, and interview with personnel, the Laboratory Director failed to ensure two (2) of two (2) Testing Personnel had documentation of training for the Sysmex XN-330 analyzer. Findings: 1. Review of the laboratory's CMS-209 form revealed the following two (2) Testing Personnel: a) Lead Medical Assistant (Testing Personnel 1); testing as of April 19, 2021 b) Testing Personnel 2; no longer employed as of May 16, 2021 2. In interview on July 26, 2021 at 9:42 am, the Lead Medical Assistant stated the laboratory started using the Sysmex XN-330 for patient testing on October 30, 2019. 3. Review of personnel records for the two (2) identified Testing Personnel revealed the laboratory did not have documentation of an initial training for the Lead Medical Assistant or Testing Personnel 2. 4. In interview on July 26, 2021 at 1:20 pm, the Lead Medical Assistant stated she could not find the Sysmex training for herself and Testing Personnel 2. 5. In interview on July 26, 2021 at 2:15 pm, the Laboratory Director stated she thinks Testing Personnel 2 took the Sysmex training documents. The Laboratory Director confirmed the laboratory did not have documentation of training for the two (2) identified Testing Personnel.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process;

	This STANDARD is not met as evidenced by: Based on record review and interview with laboratory personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Refer to D5407.