Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D0935401	11/17/2020
Name of Provider or Supplier	**Street Address, City, State**	
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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
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 surveyor review of the Proficiency Testing (PT) records and interview with the Testing Personnel (TP), the laboratory failed to maintain Work Records (WR), Attestation Statements (AS) and graded results for Hematology tests performed with the Medical Laboratory Evaluation (MLE) in M1 and M2 2020 events. The findings include: 1. The laboratory did not document handling, processing and each step in the testing and reporting of PT samples. 2. There was no raw data to substantiate reported results for event M2. 3. There were no graded results available for M1 and M2 events 4. There were no attestation statements for M1 and M2 events. 5. The TP confirmed on 11/17/20 at 10:30 am that the laboratory did not maintain records for PT events M1 and M2.
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a

	proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) evaluation records, work records and interview with Testing Personnel the laboratory failed to participate in PT for the third event in 2020 for Hematology tests with the Medical Laboratory Evaluation.
D2123	HEMATOLOGY CFR(s): 493.851(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the Testing Personnel (TP), the laboratory failed to participate in Medical Laboratories Evaluation (MLE) PT for the third event of 2020 for Hematology tests. The TP confirmed on 11/17/20 at 1:00 pm that the laboratory did not participate in the third event of 2020.
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 the lack of a procedure manual, surveyor review of the Quality Control (QC) records, proficiency testing records and interview with the Testing Personnel (TP), the laboratory failed to ensure that quality systems for the pre-analytic, analytic and post-analytical phases of Hematology testing were monitored at the date of survey. 1. The laboratory failed to maintain Proficiency Testing (PT) records. Cross refer to D2015 2. The laboratory failed to participate in PT event 3 of 2020. Cross refer to D2123. 3. The Laboratory failed to evaluate PT. Cross refer to D5211 4. The laboratory failed to monitor temperature and humidity where testing was performed. Cross refer to D5413 5. The laboratory failed to perform maintenance on the Sysmex XP-300 analyzer as required by the manufacture. Cross refer to D5429 6. The laboratory failed to perform calibration on the Sysmex XP-300 analyzer. Cross refer to D5439. 7. The laboratory failed to perform QC verification on new lots of QC. Cross refer to D5469 8. The laboratory did not maintain an accession log. Cross Refer to D5787 9. The laboratory failed to establish a procedure to verify new QC. Cross refer to D5791. 10. The laboratory failed to identify the proper TP performing testing on the Test Report. Cross refer to D5891
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 lack of Competency Assessment (CA) records and interview with the Testing Personnel (TP) and Laboratory Director (LD), the laboratory failed to establish and follow written procedures to perform a CA on one out of one TP from 3 /27/19 to the date of survey. The LD confirmed on 11/17/20 at 12:00 pm that the CA was not performed as stated above.
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 surveyor review of the Proficiency Testing (PT) records and interview with the Testing Personnel (TP), the laboratory failed to review and evaluate PT results obtained from Medical Laboratory Evaluation (MLE) for Hematology with Auto Differential events performed in 2020. The findings include: 1. There was no evidence of evaluation documentated. the "CMS performance summery" was not signed and dated for MLE-M1, M2, and M3 2. The TP confirmed on 11/17/20 at 10:45 pm that the laboratory did not review and evaluate all PT results.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks

	may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on the lack of the Procedure Manual, Sysmex XP-300 operators manual and interview with the testing personnel (TP), the laboratory failed to have written procedures for Hematology tests, assays, and examinations performed by the laboratory from 3/27/19 to the date of survey. The TP confirmed on 11/17/20 at 11:00 am that the laboratory did not have written procedures for all tests, assays, and examinations performed by the laboratory.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on surveyor review of temperature logs and interview with the Testing personnel (TP) the laboratory failed to monitor and document room temperature and humidity, and refrigerator temperature were Hematology testing were performed from 3/20/20 to the date of survey. The TP confirmed on 11/17/20 at 12:00 pm that the laboratory did not document temperature and humidity.
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 surveyor review of Manufactures Package Insert, observation of the Quality Control material, and interview with the Testing Personnel (TP), the laboratory failed to put open and new expiration dates on Hematology Control material used on the Sysmex XP-300 on the date of the survey. The TP confirmed on 11/17/20 at 1:10 pm the laboratory failed to put open and new expiration dates on the control material.
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 lack of Maintenance Records (MR) and interview with the Testing personnel (TP), the laboratory failed to perform and document maintenance as specified by the manufacturer on the Sysmex XP-300 analyzer used for Hematology tests from 3/27/19 to the date of survey. The finding includes: 1. There was no documented evidence daily, weekly or monthly maintenance was performed. 2. Approximately 10 to 15 samples were run per day. 3. The TP confirmed on 11/17/20 at 11:35 am that maintenance as specified by the manufacturer was not performed.
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 surveyor review of Calibration records and interview with the Testing Personnel (TP), the laboratory failed to perform and document Calibration procedures at least once every six months for Hematology Tests performed on the Sysmex XP-300 from April 2019 to the date of the survey. The TP confirmed on 11/17/20 at 11:30 am Calibration was not 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 lack of Quality Control (QC) records and interview with the Testing

	Personnel (TP), the laboratory failed to verify commercially assayed QC material with each new lot and/or shipment of Eightcheck-3WP X-TRA control material performed on the Sysmex XP-300 from 3/27/19 until the date of survey. The TP confirmed on 11 /17/20 at 10:15 am that the assayed values of QC material were not verified before putting in use.
D5779	CORRECTIVE ACTIONS CFR(s): 493.1282(a) Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports. This STANDARD is not met as evidenced by: Based on the lack of a Procedure Manual and interview with the Testing Personnel (TP), the laboratory failed to have a Corrective Action (CA) procedure for failed Quality Control, flagged patient results, and critical values to ensure accurate and reliable patient results from 3/27/19 to the date of the survey . The TP confirmed at 1: 00 pm on 11/17/20 the laboratory did not have the above CA procedures.
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: Based on lack of an Accession Log (AL) and interview with the Testing Personnel (TP), the laboratory failed to maintain an AL for Hematology tests from 3/27/19 until the date of survey. The TP confirmed on 11/17/18 at 12:15 pm that the laboratory did not maintain an AL for the above mentioned test.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on the lack of Procedure Manual and interview with the Testing Personnel (TP), the laboratory failed to establish a written procedure to verify new Eightcheck-3WP X-TRA Quality Control (QC) material before use for Hematology tests

	performed on the Sysmex XP-300 from 3/27/20 until the date of survey. The TP confirmed on 11/17/20 at 10:15 am that the laboratory did not have a procedure to verify new QC.
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 on surveyor review of the Test Report (TR) and interview with the Testing Personnel (TP), the laboratory failed to identify problems on the TR from 3/27/19 to the date of the survey. The finding includes: 1. Twenty of twenty TR reviewed had the statement "run by:JSS" but the but the TP's initials are DM. 2. The TP confirmed on 11 /17/20 at 12:00 pm that the laboratory failed to identify problems on the TR.
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 an surveyors review of the laboratory's records, procedures and interview with the Testing Personnel (TP) and Laboratory Director (LD), the LD failed to provide overall management and direction to the laboratory to ensure that laboratory testing is performed satisfactorily and in compliance with the CLIA regulations from January 2020 to the date of the survey. 1. The LD failed to participate in Proficiency Testing event 3 2020. Cross Refer to D2123. 2. The LD failed to perform Competency Assessment. Cross Refer D5209 3. The LD failed to have written procedures for all tests, assays, and examinations performed by the laboratory. Cross refer to D5401 4. The LD failed to ensure that PT samples were tested. Cross refer to D6016 5. The LD failed to ensure that all PT results received were reviewed by the appropriate staff to identify any problems that require corrective action. Cross refer to D6018 6. The LD failed to ensure a Quality Control program was maintained. Cross Refer to D6020. 7. The LD failed to establish a Quality Assurance plan. Cross Refer to D6021. 8. The LD failed have education and training documented for testing personnel. Cross refer to D6029 9. The LD failed to establish a Competency Assessment procedure with the applicable elements. Cross Refer to D6030. 10. The LD failed to have an approved Procedure Manual. Cross refer to D6031 11. The LD failed to specify the duties and responsibilities of Testing Personnel. Cross Refer to D6032. 12. The LD failed to ensure that quality control polices, instrument calibration records and maintenance records were followed and maintained by TP. Cross refer to D6072 13. The LD failed to identify problems that may affect test performance by not reviewing and evaluating trends and/or shifts for tests performed on the Sysmex XP-300 analyzer. Cross Refer to D6074.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES

	CFR(s): 493.1407(e)(4)(i) 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)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on surveyor review of Proficiency Testing (PT) records and interview with the Testing Personnel (TP), the Laboratory Director (LD) failed to ensure that PT samples were tested for Hematology tests in M3 of 2020 with Medical Laboratory Evaluation (MLE). The TP confirmed on 11/17/20 at 11:31 am that the LD did not ensure that PT samples were tested.
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 surveyor review of Proficiency Testing (PT) records and interview with the Testing Personnel (TP), the Laboratory Director (LD), failed to ensure that all PT results received were reviewed by the appropriate staff to identify any problems that require corrective action for Hematology performed with Medical Laboratory Evaluation (MLE) in the calendar year 2020. The TP confirmed on 11/17/20 at 10:40 am that the PT results were not reviewed.
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 surveyor review of the Quality Control (QC) records, lack of a QC procedures and interview with the Testing Personnel (TP), the Laboratory Director (LD) failed to ensure that a QC program was established for Hematology tests from 7 /31/19 to the date of survey. The findings include: 1) The wrong lot number of

	controls were entered into the analyzer and Laboratory Information System (LIS). a) Sysmex Eightcheck 3WP X-TRA-L Lot 02520710, Exp. 12-16-20, Sysmex Eightcheck 3WP X-TRA-N Lot 02520711, Exp. 12-16-20, Sysmex Eightcheck 3WP X-TRA-H Lot 02520712, Exp. 12-16-20 were the controls that were in use. b) Sysmex Eightcheck 3WP X-TRA-L Lot 13981, Exp. 7-31-19, Sysmex Eightcheck 3WP X-TRA-N Lot 91130711, Exp. 7-31-19, Sysmex and Eightcheck 3WP X-TRA-H Lot 901130712, Exp. 7-31-19 were shown as being run on the Sysmex XP-300 analyzer c) Sysmex 3WP X-TRA-L Lot 00840710, Exp. 7-1-20, Sysmex Eightcheck 3WP X-TRA-N Lot 00740710, Exp. 7-1-20, Sysmex Eightcheck 3WP X-TRA-H values entered into up in LabDaq LIS. 4) There was no evidence of QC review. 5) The TP confirmed on 11/17/20 at 10:40 am the LD did not ensure a QC plan was established and maintained.
D6021	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 quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on a lack of a Quality Assurance (QA) plan and interview with the Testing Personnel (TP), the Laboratory Director failed to establish a QA plan from 3/27/19 until the date of survey. The TP confirmed 11/17/20 at 12:05 pm that a QA plan had not been established.
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 the lack of Personnel Files (PF) and interview with the Testing Personnel (TP), the Laboratory Director failed to have education and training documented for one out of one TP from at the time of the survey. The TP confirmed on 11/17/20 at 12: 10 pm that all education and training records were not available.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) 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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on the lack of a Procedure Manual and interview with the Testing Personnel (TP), the Laboratory Director failed to establish a Competency Assessment (CA) procedure with the required elements for Hematology tests at the time of survey. The TP confirmed on 11/17/20 at 10:40 am that a CA procedure was not established.
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 the lack of a Procedure Manual (PM) and interview with the Testing Personnel (TP), the Laboratory Director failed to have an approved procedure manual available for Hematology testing from 3/27/19 to the date of the survey. The TP confirmed on 11/17/20 at 11:30 am an approved PM was not available.
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 lack of the Personnel Files (PF) and interview with the Testing Personnel (TP), the Laboratory Director (LD) failed to specify in detail the duties and responsibilities for one out of one TP engaged in the performance of Hematology

	testing at the time of survey. The TP confirmed on 11/17/20 at 12:15 am that the LD did not specify the duties and responsibilities of TP.
D6072	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(3) Each individual performing moderate complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed. This STANDARD is not met as evidenced by: Based on the lack of a procedure manual, review of quality control (QC procedures, instrument calibration and maintenance records the TP failed to document and perform the above mentioned procedures for the Sysmex XP-300 analyzer from 3/27 /19 until the date of survey. The TP confirmed on 11/17/20 at 1:00 pm that the TP failed follow and document QC calibration, and maintenance.
D6074	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(5) Each individual performing moderate complexity testing must be capable of identifying problems that may adversely affect test performance or reporting of test results and either must correct the problems or immediately notify the technical consultant, clinical consultant or director. This STANDARD is not met as evidenced by: Based on surveyor review of the Quality Control (QC) records and interview with the Testing Personnel (TP), the TP failed to identify problems that may affect test performance by not reviewing and evaluating trends and/or shifts for tests performed on the Sysmex XP-300 analyzer on the date of survey. The TP confirmed on 11/17/20 at 12:45 pm that trends and shifts were not reviewed.