Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0677022	09/06/2022
Name of Provider or Supplier	**Street Address, City, State**	
Memphis Children's Clinic	6615 Kirby Center Cove, Memphis, TN	

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
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on review of the Centers for Medicare & Medicaid Services Laboratory Personnel Report (CLIA) (Form CMS-209), review of the laboratory's proficiency testing records and interview with the lead testing person, the laboratory failed to ensure proficiency testing was performed by personnel who routinely perform patient testing when the lead testing person performed six of eight proficiency testing events reviewed for 2020, 2021 and 2022. The findings include: 1. Review of the form CMS 209 revealed three personnel who perform patient testing for complete blood count. 2. Review of the laboratory's proficiency testing attestation statements revealed that six of eight proficiency testing events reviewed were performed by the lead testing person. 3. Interview with the lead testing person on 09/06/2022 at 2:30 pm confirmed the laboratory failed to ensure proficiency testing was performed by personnel who routinely perform patient testing in 2020, 2021 and 2022.
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:

	CITATION NUMBER ONE Based on review of quality control records, document request and interview with the laboratory lead, the laboratory failed to retain manufacturer quality control (QC) assay sheets for two years for nine of twelve lots reviewed for selected dates from 2020, 2021 and 2022. The findings include: 1. Review of quality control records for complete blood count the revealed the following: QC lot numbers 068000, 078000 and 088000 in use on 11/18/2020. QC lot numbers 067600, 077600 and 087600 in use on 05/20/2021. QC lot number 2070 (levels 1, 2 and 3) in use from 03/30/2022 to 06/14/2022. QC lot number 2154 (levels 1, 2 and 3) (current lot) reviewed for 08/27/2022. 2. Request made to the laboratory lead on 09/06/2022 at 1pm for the manufacturer assay sheet for the twelve QC lots reviewed revealed the manufacturer assay sheets were not retained for 068000, 078000, 088000, 067600, 077600, 087600, and lot 2070 (Levels 1, 2, and 3). Nine of twelve assay sheets were not retained for two years. 3. Interview with the laboratory lead on 09/06/22 at 2:30 pm confirmed the laboratory failed to retain the manufacturer QC assay sheets for two years for nine of twelve lots reviewed from 2020, 2021 and 2022. CITATION NUMBER TWO Based on review of quality control (QC) records, patient test records, and interview with the laboratory lead, the laboratory failed to maintain records of quality controls in use from 04/01/2022 until 09/06/2022. 1. Review of quality control records for the Sysmex XN-330 complete blood count instrument revealed the laboratory prints and reviews the insight data from Sysmex. The reports did not include the laboratory's quality control ranges that were in use during the period the lots were used. 2. Review of the laboratory's patient test records revealed patient testing on the Sysmex XN-330 began on 04/01/2022 with approximately 550 patients reported since patient testing began. 3. Interview with the lead testing person on 09/06/2022 at 2:30 pm confirmed the laboratory failed to retain quality control limits in use since patient testing began on the Sysmex XN-330 on 04 /01/2022 until the date of the survey on 09/06/2022.
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: The laboratory failed to detect problems with proficiency testing failures (Refer to D5293), failed to have a procedure for use of the Sysmex XN-330 complete blood count (CBC) instrument (Refer to D5401), failed to monitor environmental conditions (humidity) for the use of the Sysmex XN-330 CBC instrument (Refer to D5413 citation #1), failed to define appropriate temperature ranges for storage of CBC quality control materials (Refer to D5413 citation #2), failed to have documentation of background checks for the Sysmex XN-330 CBC instrument (Refer to D5435), failed to perform quality control on dates when patients were tested (Refer to D5447), and failed to have an effective analytic quality assessment program (Refer to D5793).
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 observation of the laboratory, review of patient test records, the laboratory's testing personnel competency assessment policy, lack of documentation, and interview with the laboratory lead, the laboratory failed to follow its' own policy for assessing competency when a new laboratory test platform was introduced for patient complete blood count (CBC) testing in 2022. The findings include: 1. Observation of the laboratory on 09/06/2022 at 9 am revealed the Sysmex XN-330 in use for patient testing for complete blood count (CBC) (new since the last survey). 2. Review of patient test records revealed patient testing for CBC began on the new instrument on 04/01/2022. 3. Review of the laboratory policy for testing personnel competency revealed that employees are to be evaluated for competency when a new laboratory test or brand of laboratory test is introduced. 4. Lack of documentation of training and competency assessment for three of three testing personnel for the use of the new Sysmex XN-330 instrument. 5. Interview with the lead testing person on 09/06/2022 at 2:30 pm confirmed the laboratory failed to follow its' own competency assessment policy when it did not reassess competency for the use of the Sysmex XN-330 in 2022.
D5293	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c) (b) The general laboratory 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 general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities. This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing records and interview with the laboratory lead, the laboratory's quality assessment program was ineffective in identifying the cause of unacceptable and unsatisfactory proficiency testing scores in 2021 and 2022 (two of five events reviewed). The findings include: 1. Review of the laboratory's proficiency testing records revealed the following: 2021 event one--Score of 73% for white blood cell differential. Documented cause of failure = mixing error. Comparison of the instrument printouts to the submitted results revealed the cause of the error was clerical. The cause of the failure was not determined during the review, no corrective action was performed for the clerical error. 2022 event one Score of 80% for the red blood cell analyte. Score of 60% for the mean corpuscular volume. Score of 80% for Red Cell Distribution Width (RDW-SD). The cause of the failure was documented as a mixing error. Comparison of the instrument printout to the submitted results revealed the cause of the error for the 80% RBC score was clerical. The cause of the error for the red blood cell analyte was not determined during the review. No corrective action was performed for any of the unacceptable results. 2. Interview with the laboratory lead on 09/06/2022 at 2:30 pm confirmed the cause of the proficiency unacceptable and unsatisfactory scores was not identified for two of five proficiency testing events with 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: Based on observation of the laboratory, review of patient test records, document request, and interview with the lab lead, the laboratory failed to have a written procedure for use of the Sysmex XN-330 complete blood count (CBC) instrument from the time patient testing began on 04/01/2022 until the date of the survey on 09/06 /2022 with approximately 550 patient CBCs performed. 1. Observation of the laboratory on 09/06/2022 at 9 am revealed the Sysmex XN-330 on the counter in use for patient testing for CBC. 2. Review of patient records revealed patient testing on the Sysmex XN-330 began on 04/01/2022, with approximately 550 patient CBCs performed since testing began on 04/01/2022 until the date of the survey on 09/06 /2022. 3. Request made to the lab lead on 09/06/2022 at 10 am for the procedure for the Sysmex XN-330 revealed no procedure was available. 4. Interview with the lab lead on 09/06/2022 at 2:30 pm confirmed the laboratory did not have a written procedure for use of the Sysmex XN-330 CBC instrument in 2022.
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: CITATION NUMBER ONE: Based on observation of the laboratory, review of manufacturer specifications for operation of the Sysmex XN-330 complete blood count (CBC) instrument, patient test records, document request and interview with the laboratory lead, the laboratory failed to monitor humidity levels for the Sysmex XN-330 CBC instrument from 04/01/2022 to date of survey on 09/06/2022. 1. Observation of the laboratory on 09/06/2022 at 9 am revealed the Sysmex XN-330 (serial #14732) in use for patient testing for CBC. 2. Review of the manufacturer requirements for operation of the Sysmex XN-330 revealed an operating humidity of 20 - 85%. 3. Review of patient test records revealed the first patient CBC was performed and reported on the Sysmex XN-330 on 04/01/2022. 4. Request to the laboratory lead on 09/06/2022 at 1 pm for humidity monitoring records revealed no records were available. 5. Interview with the laboratory lead on 09/06/2022 at 2:30 pm confirmed the laboratory did not monitor the humidity levels where the Sysmex XN-330 was operated from the time testing began on 04/01/2022 until date of survey on 09/06 /2022. CITATION NUMBER TWO: Based on observation of the laboratory, review of the manufacturer quality control package insert, the laboratory maintenance logs, and interview with the laboratory lead, the laboratory failed to define temperature ranges for storage of complete blood count (CBC) controls that met the manufacturer requirements in 2022. The findings include: 1. Observation of the laboratory on 09/06

	/2022 at 9 am revealed CBC controls stored in the refrigerator. 2. Review the manufacturer package insert for the CBC controls revealed a storage temperature range of 2-8 degrees Celsius. 3. Review of the laboratory's temperature monitoring log for the refrigerator where the controls were stored revealed the following statement "Required Temperature Range: 1.7 to 7.2 degrees C." 4. Interview with the laboratory lead on 09/06/2022 at 2:30 pm confirmed the laboratory failed to define temperature ranges that were consistent with manufacturer's storage requirements for CBC controls in 2022.
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of patient test records, document request, and interview with the lead testing person, the laboratory failed to have records of background counts for the Sysmex XN-330 available to the surveyor on 09/06/2022 for dates ranging from 04/01/2022 to the date of the survey on 09/06/2022. The findings include: 1. Observation of the laboratory on 09/06/2022 at 9 am revealed the Sysmex XN-330 (serial #14732) in use for patient testing for CBC. 2. Review of patient test records revealed the first patient was tested on the Sysmex XN-330 on 04/01/2022. 3. Request to the lead testing person on 09/06/2022 at 1 pm for maintenance records including records of background counts since patient testing began on 04/01/2022 revealed no records were available. 4. Interview with the lead testing person on 09/06/2022 at 2:30 pm confirmed the laboratory did not have documentation of background counts available for surveyor review from the date testing began on Sysmex XN-330 on 04/01/2022 until the date of the survey on 09/06/2022.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on observation of the laboratory, record request and interview with the laboratory lead, the laboratory failed to verify the accuracy of their temperature recording devices in 2020, 2021, and 2022. The findings include: 1. Observation of the laboratory on 09/06/2022 at 9 am revealed the Sysmex XN-330 in use for performing patient complete blood count (CBC) testing. The observed device used for monitoring room temperature where the instrument was located was the laboratory

	thermostat. 2. Request to the laboratory lead on 09/06/2022 at 9:30 am for records of verification of accuracy of the temperature reading on the laboratory thermostat / temperature monitoring device revealed no records were available. 3. Interview with the laboratory lead on 09/06/2022 at 2:30 pm confirmed the laboratory did not have a process in place to verify the accuracy of its' temperature monitoring device in the area where the CBC instrument was in use in 2020, 2021, and 2022.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of quality control and patient records, and interview with the lead testing person, the laboratory failed to perform complete blood count (CBC) quality control on dates when patients were tested from 06/15 /2022 until 06/21/2022. A total of 19 patients were tested for CBC during the dates when there was no documentation of quality control. The findings include: 1. Observation of the laboratory on 09/06/2022 at 9 am revealed the Sysmex XN-330 (serial #14732) in use for patient testing for CBC. 2. Review of the laboratory's quality control and patient test records revealed patient testing performed on the following dates when there was no documentation of CBC quality control: 06/15 /2022--3 patients 06/16/2022--1 patient 06/17/2022--3 patients 06/18/2022--4 patients 06/20/2022--4 patients 06/21/2022--4 patients 3. Interview with the lead testing person on 09/06/2022 at 2:30 pm confirmed there was no documentation that CBC quality control was performed for six dates in June 2022 with a total of 19 patient CBCs performed.
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 of the laboratory, review of patient test records, quality assurance records, document request, and interview with the laboratory lead, the laboratory's quality assessment process was ineffective in detecting and correcting problems with quality control and maintenance activities for the Sysmex XN-330 complete blood count (CBC) instrument from the time patient testing began on 04/01 /2022 until the date of the survey on 09/06/2022. The findings include: 1. Observation of the laboratory on 09/06/2022 at 9 am revealed the Sysmex XN-330 CBC instrument on the counter in use for patient testing for CBC. 2. Review of patient test records revealed that patient testing for CBC on the XN-330 began on 04/01/2022. 3.

	Review of monthly quality assurance records since testing began in April 2022 revealed the following: CBC controls "All in range?"=Yes Startups-- " Pass" = Yes Levey-Jennings graphs "Without severe up or down trends? = Yes The same documentation was present for the months of April, May, June, July and August 2022. For the month of June 2022 the quality assessment records did not indicate any identification or correction for the dates patients were tested with no quality control performed (Refer to D5447). 4. Request for quality control records including daily quality control, background counts and Levy-Jennings graphs since testing began on 04/01/2022 revealed no documents were available. 5. Interview with the laboratory lead on 09/06/2022 at 2:30 pm confirmed no quality control / maintenance documents for the Sysmex XN-330 CBC instrument were available. There were no background counts, daily quality control records to include laboratory quality control ranges, and Levy-Jennings graphs. The lead testing person further stated she did not know how to print any of those reports due to a lack of training. The laboratory's quality assessment program was ineffective in preventing problems with review and retention of quality control and maintenance records for the Sysmex XN-330 in 2022 from the date patient testing began on 04/01/2022 until the date of the survey on 09/06/2022. Further, it was ineffective in detecting that there was no documentation of quality control on dates when patient were tested in the month of June 2022.
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: The laboratory director failed to approve validation procedures for the use of the Sysmex XN-330 (Refer to D6013), failed to ensure proficiency testing samples were tested as required under subpart H (Refer to D6016), failed to ensure proficiency testing reports were review by appropriate staff and issues with proficiency testing identified and corrected (Refer to D6018), failed to ensure the quality control program was maintained (Refer to D6020), failed to ensure quality assessment programs were maintained (Refer to D6021), failed to ensure the quality control and quality assessment program was maintained and failures identified (Refer to D6022), failed to ensure testing personnel were trained on the use of the Sysmex XN-330 complete blood count instrument (Refer to D6029), failed to ensure testing personnel competency assessment policies were followed (Refer to D6030), and failed to ensure an approved procedure manual was available for the use of the Sysmex XN-330 complete blood count instrument (Refer to D6031).
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 of the laboratory, review of instrument validation records, review of patient test records and interview with the lead testing person, the laboratory director failed to ensure verification procedures were adequate for the Sysmex XN-330 complete blood count (CBC) instrument in 2022. Patient testing began on 04/01 /2022 with approximately 550 patients reported since patient testing began. The findings include: 1. Observation of the laboratory on 09/06/2022 at 9 am revealed the Sysmex XN-330 on the counter in use for performing patient testing for complete blood count (CBC). 2. Review of validation studies performed for the Sysmex XN-330 revealed the method comparison and carryover studies had not been approved by the laboratory director who functions as the technical consultant. 3. Review of patient records revealed patient testing for CBC on the Sysmex XN-330 began on 04/01 /2022. A CBC activity report provided by the laboratory indicated approximately approximately 550 patients had been performed since patient testing began. 4. Interview with the laboratory lead on 09/06/2022 at 2:30 pm confirmed the laboratory director did not verify the comparison and carryover studies for the Sysmex XN-330 in 2022. Patient testing began on 04/01/2022 with approximately 550 patients reported since testing began.
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 review of the Centers for Medicare & Medicaid Services Laboratory Personnel Report (CLIA) (Form CMS-209), review of the laboratory's proficiency testing records and interview with the lead testing person, the laboratory director failed to ensure proficiency testing samples were tested as required under subpart H in 2020, 2021, and 2022 (Refer to D2007). The findings include: 1. Review of the form CMS 209 revealed three personnel who perform patient testing for complete blood count. 2. Review of the laboratory's proficiency testing attestation statements revealed that six of eight proficiency testing events reviewed were performed by the lead testing person. 3. Interview with the lead testing person on 09/06/2022 at 2:30 pm confirmed the laboratory director failed to ensure proficiency testing was performed by personnel who routinely perform patient testing in 2020, 2021 and 2022 (Refer to D2007).
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 review of the laboratory's proficiency testing records and interview with the laboratory lead, the laboratory director failed to ensure proficiency testing reports were reviewed by the appropriate staff to identify the cause of proficiency testing failures and apply corrective action in 2021 and 2022 (two of five events reviewed) (Refer to D5293). The findings include: 1. Review of the laboratory's proficiency testing records revealed the following: 2021 event one--Score of 73% for white blood cell differential. Documented cause of failure = mixing error. Comparison of the instrument printouts to the submitted results revealed the cause of the error was clerical. The cause of the failure was not determined during the review, no corrective action was performed for the clerical error. 2022 event one Score of 80% for the red blood cell analyte. Score of 60% for the mean corpuscular volume. Score of 80% for Red Cell Distribution Width (RDW-SD). The cause of the failure was documented as a mixing error. Comparison of the instrument printout to the submitted results revealed the cause of the error for the 80% RBC score was clerical. The cause of the error for the red blood cell analyte was not determined during the review. No corrective action was performed for any of the unacceptable results. 2. Interview with the laboratory lead on 09/06/2022 at 2:30 pm confirmed the laboratory director failed to ensure the cause of the unacceptable and unsatisfactory proficiency testing scores were identified and corrective action applied for two of five events with scores less than 100% (Refer to D5293).
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 of the laboratory, review of quality control and patient records, the laboratory procedure manual, and interview with the lead testing person, the laboratory director failed to ensure the laboratory's general quality control plan was maintained for six dates in June 2022 (Refer to D5447) and failed to ensure a specific quality control plan for the Sysmex XN-330 complete blood count (CBC) was available (Refer to D5401 and D6031). The findings include: 1. Observation of the laboratory on 09/06/2022 at 9 am revealed the Sysmex XN-330 (serial #14732) in use for patient testing for CBC. 2. Review of the laboratory's quality control and patient test records revealed patient testing performed on the following dates when there was no documentation of CBC quality control: 06/15/2022--3 patients 06/16/2022--1 patient 06/17/2022--3 patients 06/18/2022--4 patients 06/20/2022--4 patients 06/21 /2022--4 patients 3. Review of the laboratory procedure titled "THE LABORATORY'S GENERAL LABORATORY POLICIES" revealed that "Quality control samples are analyzed each day (as outlined in the technical procedure

	manual), and must be within acceptable limits before patient samples may be analyzed." No quality control procedure for the Sysmex XN-330 was available and no technical procedure manual was available on the date of the survey (Refer to D5401 and D6031). 4. Interview with the lead testing person on 09/06/2022 at 2:30 pm confirmed the laboratory director failed to ensure the laboratory general quality control policy was followed in June 2022, and failed to ensure a technical procedure manual and quality control procedure for the Sysmex XN-330 was implemented from the date of patient testing on 04/01/2022 until the date of the survey on 09/06/2022.
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 observation of the laboratory, review of patient test records, quality assurance records, document request, and interview with the laboratory lead, the laboratory director failed to ensure the laboratory's quality assessment program was maintained for the Sysmex XN-330 complete blood count (CBC) instrument from the time patient testing began on 04/01/2022 until the date of the survey on 09/06/2022 (Refer to D5793). The findings include: 1. Observation of the laboratory on 09/06 /2022 at 9 am revealed the Sysmex XN-330 CBC instrument on the counter in use for patient testing. 2. Review of patient test records revealed that patient testing for CBC on the XN-330 began on 04/01/2022. 3. Review of monthly quality assurance records since testing began in April 2022 revealed the following: CBC controls "All in range?" =Yes Startups-- " Pass" = Yes Levey-Jennings graphs "Without sever up or down trends? = Yes The same documentation was present for the months of April 2022, May 2022, June 2022, July 2022, and August 2022. The section for "TC Reviewed Data/Comments" was signed by the lab lead who does not meet the technical consultant education requirements. All documents were reviewed by the laboratory director. 4. Request for quality control records including daily quality control, background counts and Levy-Jennings graphs since testing began on 04/01/2022 revealed no documents were available. 5. Interview with the laboratory lead on 09/06 /2022 at 2:30 pm confirmed no quality control documents for the Sysmex XN-330 CBC instrument were available. There were no background counts, daily quality control records to include laboratory quality control ranges, and Levy-Jennings graphs. The lead testing person further stated she did not know how to print any of those reports due to a lack of training. The laboratory director failed to ensure the quality assessment control program for the CBC instrument was maintained beginning 04/01/2022 until the date of the survey on 09/06/2022 (Refer to D5793).
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 of the laboratory, review of quality control and patient records, quality assurance records and interview with the lead testing person, the laboratory director failed to identify quality failures when no corrective actions were performed for the month of June 2022. Patient CBCs were performed and reported from 06/15 /2022 until 06/21/2022 with no quality control performed prior to patient testing as required by policy. A total of 19 patients were tested for CBC during the dates when there was no documentation of quality control (Refer to D5447). The findings include: 1. Observation of the laboratory on 09/06/2022 at 9 am revealed the Sysmex XN-330 (serial #14732) in use for patient testing for CBC. 2. Review of the laboratory's quality control and patient test records revealed patient testing performed on the following dates when there was no documentation of CBC quality control: 06/15 /2022--3 patients 06/16/2022--1 patient 06/17/2022--3 patients 06/18/2022--4 patients 06/20/2022--4 patients 06/21/2022--4 patients 3. For the month of June 2022 the quality assessment records did not indicate that the failure to perform quality control prior to patient testing was identified and there was no evidence of corrective action for the dates when patients were tested with no quality control performed (Refer to D5447). 3. Interview with the lead testing person on 09/06/2022 at 2:30 pm confirmed the laboratory director failed to identify quality failures for the month of June 2022 for dates when there was no documentation that CBC quality control was performed for six dates with a total of 19 patient CBCs performed.
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 observation of the laboratory, document request, review of patient complete blood count (CBC) test records and interview with the laboratory lead, the laboratory director failed to ensure three of three testing personnel were trained on the use of the Sysmex XN-330 CBC instrument prior to patient testing in 2022, with approximately 550 patient CBCs performed by untrained testing personnel since patient testing began on 04/01/2022. The findings include: 1. Observation of the laboratory on 09/06 /2022 at 9 am revealed the Sysmex XN-330 CBC instrument in use for patient testing (new since the last survey date). 2. Request made to the lab lead on 09/06/2022 at 10 am for training records for the use of the Sysmex XN-330 revealed no documents were available for three of three testing personnel. 3. Review of test records revealed patient testing for CBC on the Sysmex XN-330 began on 04/01/2022. A CBC activity report provided by the laboratory revealed that approximately 550 patient CBCs have

	been reported since patient testing began. 4. Interview with the laboratory lead on 09 /06/2022 at 10 am confirmed the laboratory director failed to ensure testing personnel were trained on the use of the Sysmex XN-330 CBC instrument in 2022 and demonstrated accuracy in using the Sysmex XN-330 prior to patient testing which began on 04/01/2022.
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 observation of the laboratory, review of the laboratory procedure manual, the laboratory's testing personnel competency assessment documents and interview with the lead testing person, the laboratory director failed to ensure competency assessment policies were followed when the director did not perform annual competency assessments for three of three testing personnel in 2022 and did not re-evaluate competency for the use of the Sysmex XN-330 complete blood count instrument before patient testing began on 04/01/2022. The findings include: 1. Observation of the laboratory on 09/06/2022 at 9 am revealed the Sysmex XN-330 in use for patient testing for complete blood count (CBC) (new since the last survey-date in use was 04/01/2022). 2 . Review of the laboratory's testing personnel policy revealed that competency would be performed when any new test platform is introduced. 3. Review of the laboratory's testing personnel competency assessment documents revealed that the 2022 annual competency assessments had not been performed by the laboratory director for three of three testing personnel. The signature on the form for the lead testing person did not match the lab director/technical consultant signature, and the competency assessments for the other two personnel did not include any signatures of the laboratory director. No competency assessments were available for the use of the new Sysmex XN-330 instrument. 2. Interview with the lead testing person on 09/06/2022 at 2:30 pm confirmed the lab director did not perform annual competencies for three of three testing personnel in 2022 and failed to follow the policy for competency assessment for the use of the new CBC instrument in 2022.
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 observation of the laboratory, document request, review of patient test records and interview with the laboratory lead, the laboratory director failed to ensure an approved procedure manual was available for the use of the Sysmex XN-330 complete blood count (CBC) instrument in 2022 (Refer to D5401). The findings include: 1. Observation of the laboratory on 09/06/2022 at 9 am revealed the Sysmex XN-330 on the counter in use for patient testing for CBC. 2. Request made to the lab lead on 09/06/2022 at 10 am for an approved procedure manual for the use of the Sysmex XN-330 revealed no procedure was available (Refer to D5401). 3. Review of patient test records revealed patient testing for CBC on the Sysmex XN-330 began on 04/01/2022. 4. Interview with the lab lead on 09/06/2022 at 2:30 pm confirmed the laboratory director failed to ensure an approved procedure manual was available for the use of the Sysmex XN-330 from the time patient testing began on 04/01/2022 until the date of the survey on 09/06/2022.