Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	18D1025761	02/21/2024
Name of Provider or Supplier	**Street Address, City, State**	
Norton Cancer Institute	131 Stonecrest Road Suite 100, Shelbyville, KY	

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 conducted on 02/21/2024. The facility was found to not be in compliance with the laboratory requirements of 42 CFR Part 493 with standard deficiencies cited.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of laboratory policy, patient records, and confirmed in staff interview, the laboratory failed to follow their own policy for manual differentials for three (3) of fifteen (15) patients. Findings include: 1. The Laboratory policy titled, "Criteria for Manual Differential & Pathologist" review stated: "Q-flags displayed on

	the NCI hemogram that show EITHER: Blast, lymphoblast, or Atypical Lymphocyte (above 30%) warrant manual differential testing. This criteria only applies to NCI patients who have NOT had a manual differential within the last 30 days." 2. Further review of the laboratory policy titled, "Reporting result and Procedure Limitations" stated: "Nucleated RBC's. Perform manual differential and correct Sysmex XS-1000i WBC count for the NRBC's per 100 WBC's counted. WBC = XS WBC count x 100 /100 + NRBC" 3. Review of fifteen (15) patient records from 2023 revealed the laboratory failed to follow their policy for the following patients: a. EP02870076 - NRBC Flag - No documentation of corrected WBC count b. EP00564150 - NRBC Flag - No documentation of corrected WBC count c. EP01335558 - Atypical Lympho? Flag - No documentation of manual differential 4. In an interview on 2/21 /2024 at 4;10 PM in break room, TC1 was asked to provide documentation of performance of a manual differential or correction of white blood cell count. No documentation was provided. TC1 confirmed three (3) of the fifteen (15) patients met the requirements for manual differential, but a manual differential was not performed. Word Key: WBC= White Blood Cell
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: I. Based on direct observation, review of manufacturer's instructions, laboratory environmental records, and confirmed in staff interview, the laboratory failed to establish an acceptable room temperature range for twelve (12) of twelve (12) months. Findings include: 1. The following testing materials were observed on 2/21/2024 at 12: 20 PM in the testing area: a. Becton Dickinson (BD) Vacutainer K2 Ethylenediaminetetraacetic Acid (EDTA), Lot 3289496, 1.5 packages b. BD Vacutainer Serum Separator Tube (SST), Lot 3353595, 1.5 packages c. BD Vacutainer Plasma Separating Tube (PST), Lot 3290681, 1.5 packages. 2. Manufacturer's Instructions located on the label of each package indicated a temperature requirement of 4 degrees Celsius to 25 degrees Celsius. 3. Review of the laboratory's temperature logs from January 2023 through December 2023, revealed the laboratory's acceptable temperature range of 15.6 to 29.4 degrees Celsius. This range exceeded the specified range for the BD Collection tubes stored in the testing area. 4. In an interview on 02/21/2024 at 12:21 PM in the drawing area, the TC2 stated that the temperature range was 15.6 degrees Celsius to 29.4 degrees Celsius and confirmed that this range did not meet specifications for BD collection tubes. II. Based on direct observation, review of Sysmex XS 1000i instructions for use, laboratory environmental records (July 2022, June 2023, October 2023, and January 2024), and confirmed in staff interview, the laboratory failed to ensure that humidity levels were within manufacturer's specified ranges for the Sysmex XS-1000i Hematology Analyzer for four (4) of four (4) months and that humidity levels were within manufacturer's specifications for eighteen (18) of seventy-two (72) days. Findings include: 1. During a tour of the laboratory on 02/21/2024 at 11:59 a.m., a

	Sysmex XS-1000i Hematology Analyzer (Serial Number 75091) was observed to be in use. 2. The Sysmex XS-1000i instructions for use (date of last revision June 2013) stated, "Relative Humidity should be within the range of 30%-85%." 3. Review of the laboratory environmental logs (July 2022, June 2023, October 2023, and January 2024) revealed the laboratory's acceptable humidity range of 20%-75%. This range exceeded the manufacturer's lower acceptable range of 30%. 4. Further review of the laboratory's environmental logs revealed the following dates and humidity readings that were not within the manufacturer's acceptable range (20%-75%): October 10, 2023 29% January 2, 2024 26% January 3, 2024 29% January 4, 2024 25% January 5, 2024 26% January 8, 2024 27% January 9, 2024 28% January 10, 2024 26% January 11, 2024 25% January 12, 2024 25% January 16, 2024 24% January 17, 2024 25% January 18, 2024 24% January 19, 2024 27% January 22, 2024 25% January 23, 2024 28% January 30, 2024 27% January 31, 2024 28% 5. In an interview on 02/21/2024 at 2:02 p.m. in the breakroom, the technical consultant (TC), after review of the documentation, confirmed the findings.
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 direct observation, review of Sysmex XS-1000i Hematology Analyzer instructions for use, laboratory policy, laboratory maintenance records (July 2022, Jun 2023, October 2023, and January 2024) for the Sysmex XS-1000i Hematology Analyzer, and confirmed in staff interview, the laboratory failed to document monthly maintenance for four (4) of four (4) months. Findings include: 1. During a tour of the laboratory on 02/21/2024 at 11:59 a.m., a Sysmex XS-1000i Hematology Analyzer (Serial Number 75091) was observed to be in use. 2. The Sysmex XS-1000i instructions for use (date of last revision June 2013) stated, "Carry out monthly maintenance every month." 3. The laboratory policy for the Sysmex XS-1000i titled, "Sysmex XS-1000i Maintenance," stated "Maintenance will be performed on a daily and monthly basis." 4. The laboratory maintenance logs stated, "As needed Maintenance: Monthly Rinse." Further review of laboratory maintenance records revealed the laboratory failed to document performance of the monthly rinse in July 2022, June 2023, October 2023, and January 2024. 5. In an interview on 02/21/2024 at 2:00 p.m. in the breakroom, the technical consultant (TC) was asked to provide documentation of monthly maintenance for the Sysmex XS-1000i. No documentation was provided. This confirmed the finding.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit

	of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of laboratory calibration records and confirmed in staff interview, the laboratory failed to perform calibration verification for one (1) of two (2) intervals in 2023 for the Sysmex XS-1000i Hematology Analyzer. Findings include: 1. Review of the laboratory's calibration records for 2023 for the Sysmex XS 1000i Hematology Analyzer revealed the laboratory performed six (6) month calibration verification in February 2023. The next calibration verification was due in August 2023. 2. Further review of the laboratory's calibration records revealed the laboratory did not perform six (6) month calibration verification until December 2023, four (4) months after the due date. 3. In an interview on 02/21/2024 at 2:08 p.m. in the breakroom, the technical consultant (TC) was asked to provide documentation of calibration verification performed in August 2023. No documentation was provided. This confirmed the findings.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of laboratory procedures, laboratory quality control records (January 2023 - January 2024) and confirmed in staff interview, the laboratory failed to monitor the accuracy and precision of the Sysmex XS-1000i hematology analyzer test performance over time for thriteen (13) of thirteen (13) months. Findings included: 1. Review of laboratory procedure titled, "Sysmex XS-1000i Operation", revealed the laboratory failed to have a procedure for monitoring the accuracy and precision of test performance over time. 2. A random review of the quality control (QC) records (01 /2023 - 01/2024) revealed no documentation of monitoring QC over time. 3. In an interview on 02/21/2024 at 3:24 pm in the laboratory area, the Laboratory Manager

	was asked for documentation of monitoring QC over time for the Sysmex XS-1000i hematology analyzer. No documentation was provided.
D5461	CONTROL PROCEDURES CFR(s): 493.1256(d)(6)(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--Perform control material testing as specified in this paragraph before resuming patient testing when a complete change of reagents is introduced; major preventive maintenance is performed; or any critical part that may influence test performance is replaced. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on direct observation, review of laboratory policies, and confirmed in staff interview, the laboratory failed to establish a policy to perform Quality control (QC) testing after a change of reagents. Findings include: 1. Observed on 2/21/2024 at 12: 00 PM in the testing area, TP1 described the change of reagents procedure for the Sysmex XS-1000i Hematology analyzer. TC 1 was asked to provide documentation of the dates/times when reagents were changed on the Sysmex XS-1000i. No documentation was provided. 2. Review of the Laboratory's policies revealed the laboratory failed to establish a policy to perform QC after reagent changes. 3. In an interview on 2/21/2024 at 12 PM in the testing area, TC1 was asked if controls were run after a change in reagent. She stated that she did not run controls after changing the reagents on the Sysmex XS-1000i. This confirmed the findings.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on review of the Centers for Medicare and Medicaid (CMS) 209 form, laboratory policy, review of personnel records (2022 and 2023), and interview with the Technical Consultant (TC1), the Technical Consultant failed to document annual competency assessment for one (1) of two (2) testing persons in 2023. Findings include: 1. The laboratory's submitted CMS-209 listed two (2) testing persons (TP1, TP2). 2. The laboratory's Training and Competency Assessment of Waived and Nonwaived Testing Personnel policy stated, "the competency of those individuals performing nonwaived testing is assessed at the laboratory (CAP/CLIA number) where testing is performed ." 3. Review of personnel records from 2022 to 2023 revealed the TC failed to perform competency assessment for TP2 in 2023. 4. In an interview on 02/21/2024 at 11:30 AM in the break room, the TC confirmed annual competency for TP2 was not assessed in 2023.