Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	22D2061396	03/12/2024
Name of Provider or Supplier	**Street Address, City, State**	
Labcorp At St Vincent Cancer & Wellness	One Eaton Place Suite 301, Worcester, MA	

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 American Proficiency Institute (API) proficiency testing (PT) record review and interview with the laboratory consultant (LC) and testing personnel #1 (TP1), the laboratory failed to maintain a copy of PT attestation sheets in the specialty of Hematology. Findings include: 1. Record review on 3/4/2024 of the laboratory's 2023 API Hematology PT records revealed, the laboratory did not have a copy of the attestation sheet signed by the analyst and laboratory director for 2023 Events 1 and 2. 2. Interview with the LC and TP1 on 3/4/2024 at 11:00 AM confirmed the above findings. 3. The laboratory performs 46,800 tests annually in the specialty of Hematology.
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 surveyor observation, record review, and interview with the the laboratory consultant (LC) and testing personnel #1 (TP1), the laboratory failed to follow the procedure manual as written in the specialty of Hematology. Findings include: 1. Surveyor observation of the laboratory on 3/4/2024 at 11:00 AM revealed: a. A strip of black and yellow tape running across the laboratory, sectioning off an area that includes the entry door. b. Side 1 of the tape is the laboratory specimen and reagent refrigerators, laboratory processing area and Hematology testing equipment. c. Side 2 of the tape is a refrigerator marked, 'Refrigerator for food only," containing 2 cups of yogurt, 2 bottles of water, a bottle of creamy Caesar salad dressing and 4 plastic containers of food. Beside this refrigerator is a paper bag containing a plastic bag with bread in it. Hanging on the wall approximately 2 feet from this refrigerator is a rack with 3 laboratory coats hanging on it. The laboratory door is on this side of the tape. 2. Record review on 3/13/2024 of the laboratory's, 'Engineering and Work Practice Controls' procedure, section 7.0, Work Control Practice, item 7.2 revealed, "Food, beverages, medication and food handling containers or equipment may not be stored in refrigerator, drawers, cabinets etc. in laboratory areas and other areas where specimens or specimen waste is processed or stored." 3. Staff interview with the LC and TP1 on 3/4/2024 at 11:30 AM confirmed the findings in 1a, b, and c above. TP1 stated, "We don't have anywhere else to store our lunch." 4. The laboratory performs 46,800 tests annually in the specialty of Hematology.
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 record review and interview with the laboratory consultant (LC) and testing personnel #1 (TP1), the laboratory failed to document centrifuge function checks every 6 months to ensure platelet poor plasma (PPP) for accurate and reliable test results for the Prothrombin Time (PT) test in the specialty of Hematology. Findings include: 1. Record review on 3/4/2024 of the laboratory's centrifuge maintenance and function checks records for the centrifuge used to spin blood collection tubes for coagulation studies, revealed a lack of documentation for PPP studies in 2022, 2023 and 2024 to date. 2. Staff interview with the LC and TP1 on 3/4/2024 at 12:30 PM confirmed that PPP performance checks were not performed in 2022, 2023 and 2024 to date. TP1 stated, "We draw blue top tubes for the PT test and if there is a delay in pick-up, we will spin and aliquot the plasma to be sent to the main laboratory for testing." "It doesn't happen often that there is a delay. It is mostly at the end of the day."
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 quality control (QC) record review and interview with the laboratory consultant (LC) and Testing personnel #1 (TP1)the laboratory failed to monitor QC results over time to detect shifts and trends in the specialty of Hematology. Findings include: 1. Record review on 3/4/2024 of the laboratory's 2023 Hematology Insight QC records for the Sysmex XS-1000i revealed, the laboratory did not send QC results to the Insight program to monitor QC shifts and trends from January 2023 through October 2023, (10 of 12 months). 2. Record review on 3/4/2024 of the laboratory's, 'Sysmex XS1000i CLSI Procedure: Complete Blood Count of Whole Blood on the Sysmex XS-1000i' revealed: a. Section V: Quality Control, Item J: Insight Quality Assurance Program (QAP). "The Technical Supervisor is responsible for saving the data to a USB flash drive and uploading the data to the Sysmex Insight on the Sysmex website. Data must be submitted no later than 3 days after the due date on the Sysmex e-Check/ e-check(XS) assay sheet." 3. Staff interview on 3/4/2024 with the LC and TP1 confirmed the above findings. TP1 stated, "We did not have a supervisor at the time, so the laboratory director had to take on that role. When we found out about it, we generated a quality assurance event." 4. The laboratory performs 46,800 tests annually in the specialty of Hematology.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on record review and interview the laboratory consultant (LC) and testing personnel #1 (TP1) the laboratory failed to ensure the reference ranges on the Male (M) and Female (F) final patient test report (FPTR) matched the reference ranges in the procedure manual (PM) in the specialty of Hematology. Findings include: 1. Record review on 3/4/2024 of a male and female FPTR compared to the procedure manual revealed the following differences for white blood cell count (WBC), red blood cell count (RBC), Hemoglobin (HGB), Hematocrit (HCT), Mean Corpuscular Volume (MCV), Mean Corpuscular Hemoglobin (MCH), Mean Corpuscular Hemoglobin Concentration (MCHC), Red Cell Distribution Width (RDW), Neutrophil Percent (N%), Lymphocyte Percent (L%), Monocyte Percent (M%), Eosinophil Percent (E%), Basophil Percent (B%), Neutrophils Absolute (NA), Lymphocytes Absolute (LA), Monocytes Absolute (MA), Eosoinophils Absolute (EA), and Basohpils Absolute (BA) . Note: NE = Not established is written on the FPTR NL = Not listed on the FPTR Male Test FPTRM PM WBC 3.4-10.8 3.9-11 RBC 4.14-5.8 4.3-5.8 HGB 13.0-17.7 12.5-17.0 HCT 37.5-51.0 36.0-50.0 MCV 79-97 80-100 MCH 26.6-33.0 27-33 MCHC 31.5-35.7 31-36 RDW 11.6-15.4 11.4-14.4 N% NE 15-35 L% NE 15-60 M% NE 0-9 E% NE 0-7 B% NE 0-3 NA 1.4-7.0 NL LA 0.7-3.1 NL MA 0.1-0.9 NL EA 0.0-0.4 NL BA 0.0-0.2 NL Female Test FPTR PM WBC 3.4-10.8 3.9-11 RBC 3.77-5.28 3.70-5.10 HGB 11.1-15.9 11.5-15.0 HCT 34.0-46.6 34.0-44.0 MCV 79-97 80-100 MCH 26.6-33.0 27-33 MCHC 31.5-35.7 31-36

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