Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D2121304	05/26/2021
Name of Provider or Supplier	**Street Address, City, State**	
Northwest Regional Cancer Care Center	171 Carraway Drive, Winfield, AL	

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
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 a review of the Hematology calibration records, a review of the Beckman Coulter AcT Diff 2 Operator's Manual, and an interview with Testing Personnel #1, the laboratory failed to follow the manufacturer's instructions to perform Reproducibility, Carryover, and Calibration in the manufacturer's required order. This was noted on three of five 2019-2021 calibrations reviewed. The findings include: 1. A review of Hematology records revealed the Beckman Coulter AcT Diff 2 was calibrated on the following dates: a. 09/25/2019 with Reproducibility completed at 12:34, Carryover at 12:18, and Calibration at 12:55. b. 04/28/2020 with Reproducibility completed at 13:26, Carryover at 13:07, and Calibration at 13:44. c. 10/29/2020 with Reproducibility completed at 12:36, Carryover at 12:00, and Calibration at 12:18. 2. A review of the Beckman Coulter AcT Diff Operator's Guide revealed: a. in Chapter 5 Calibration (Page 5-2) "...Before Calibrating, you must first prepare the instrument: 1. Do Heading 5.3, Precalibration Checks. 2. Do Heading 5.4 Reproducibility. 3. Do Heading 5.5, Carryover..." b. in Heading 5.5 Carryover (Page 5-7) "...1 Be sure that you completed Reproducibility..." c. in Heading 5.6 Auto-Calibration (Page 5-10) "...1

	Be sure that you completed the Reproducibility and Carryover procedures.." 3. During an interview on 05/26/2021 at 11:40 AM, Testing Personnel #1 confirmed on 09/25 /2019 Carryover was performed before Reproducibility, on 04/28/2020 Carryover was performed before Reproducibility, and on 10/29/2020 Carryover then Calibration was performed before Reproducibility.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on a review of a test report and an interview with Testing Personnel #1 and #4, the laboratory failed to include the name and address of the laboratory where the test was performed on the test report. This was noted on one out of one test report for Complete Blood Count (CBC) reviewed by the surveyor. The findings include: 1. A review of a CBC test report from the Electronic Medical Record (EMR) revealed Internal Lab "Southeast Physician Network P.C. P.O. Box 830525 Birmingham, AL 352830525". Performing laboratory of this CBC was Northwest Regional Cancer Care Center - 171 Carraway Drive Winfield, AL 35594. 2. During an interview on 05/26 /2021 at 12:20 PM, Testing Personnel #1 and #4 confirmed the laboratory name and address are not on the test report from the Electronic Medical Record for CBC report reviewed and the name/address on the report are the owners.
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 a review of patient test reports and instrument printout of results (chart audits), a review of quality assurance records (QA) and an interview with Testing Personnel #1 and #4, the laboratory failed identify the reference intervals for Complete Blood Count (CBC) were different from the patient test reports and the instrument printout of results. The findings include: 1. A review of patient A's instrument printout revealed the following reference intervals: a. White Blood Count 4.5 -10.5 b. Lymphocytes 20.5 - 51.1 c. Monocytes 1.7 - 9.3 d. Granulocyte 42.2 - 75.2 e. Lymphocytes Absolute 1.2 - 3.4 f. Monocytes Absolute 0.1 - 0.6 g. Granulocyte Absolute 1.4 - 6.5 h. Red Blood Cell 4.00 - 6.00 i. Hemoglobin 11.0 - 18.0 j. Hematocrit 35.0 - 60.0 k. Mean Corpuscular Volume 80.0 - 99.9 l. Mean Corpuscular Hemoglobin 27.0 - 31.0 m. Mean Corpuscular Hemoglobin Concentration 33.0 - 37.0 n. Red Blood Cell Distribution Width 11.6 - 13.7 o. Platelet

	Count 150 - 450 p. Mean Platelet Volume 7.8 - 11.0 2. A review of patient A's patient test report (from the Electronic Medical Record (EMR)) revealed the following reference intervals: a. White Blood Count 4.1 -10.9 b. Lymphocytes 10.0 - 58.5 c. Monocytes 0.1 - 24.0 d. Granulocyte 37.0 - 92.0 e. Lymphocytes Absolute 0.6 - 4.1 f. Monocytes Absolute 0.0 - 1.8 g. Granulocyte Absolute 2.0 - 7.8 h. Red Blood Cell 4.20 - 6.30 i. Hemoglobin 12.0 - 18.0 j. Hematocrit 37.0 - 51.0 k. Mean Corpuscular Volume 80.0 - 97.0 l. Mean Corpuscular Hemoglobin 26.0 - 32.0 m. Mean Corpuscular Hemoglobin Concentration 31.0 - 36.0 n. Red Blood Cell Distribution Width 11.5 - 14.5 o. Platelet Count 140 - 440 p. Mean Platelet Volume 7.8 - 11.0 3. A review of quality assurance records (QA) revealed the laboratory had performed chart audits monthly from May 2019 to April 2021. The quality assessment form included a column for Test Report containing normal ranges on the report, and this was marked "y" (yes). The laboratory staff failed to identify the reference intervals were different from the patient test report (from the EMR) and the instrument printout. 4. During an interview on 05/26/2021 at 12:20 PM, Testing Personnel #1 and #4 confirmed the patient test report (from the EMR) and the instrument printout had different reference intervals for Complete Blood Count (CBC).