Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0687538	01/06/2021
Name of Provider or Supplier	**Street Address, City, State**	
Dothan Hematology And Oncology Pc	287 Healthwest Drive, Dothan, 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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on a review of College of American Pathologists (CAP) Proficiency Testing (PT) records and an interview with Testing Personnel #1, the Laboratory Director and Testing Personnel failed to sign the attestation statement for eight out of eight 2018 - 2020 Hematology PT events. The findings include: 1. A review of CAP PT records revealed the attestation statements for 2018 FH2 - B, 2018 FH2 - C, 2019 FH2 - A, 2019 FH2 - B, 2019 FH2 - C, 2020 FH2 - A, and 2020 FH2 - B were not signed by the Laboratory Director/delegate and the testing personnel. Also, 2020 FH2 - C was not signed by the Laboratory Director. 2. During an interview with Testing Personnel #1 on 01/06/2021 at 12:55 PM, the surveyor reviewed the instructions on the attestation statement which specified the Laboratory Director and testing personnel must physically sign the document. Testing Personnel #1 explained once the laboratory began entering the results electronically, they had not realized signing the statement was still required. .
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 reviews of the Beckman Coulter AcT diff 2 Hematology analyzer Operator's Manual, calibration and quality control (QC) records, and interviews with Testing Personnel #1, the laboratory failed to follow the manufacturer's instructions to verify calibrations by running quality controls (QC), for ten out of eleven calibrations performed on the two Hematology analyzers in 2018 - 2020. In addition, the laboratory failed to ensure at least two levels of quality control were performed and acceptable, prior to analyzing patient specimens and reporting the results on five out of the eleven days the instrument was calibrated. The findings include: 1. During the entrance tour on 1/6/2021 at approximately 11:30 AM, Testing Personnel #1 stated the only test performed on site were CBC's (Complete Blood Counts) on two Beckman Coulter AcT diff 2 Hematology analyzers: SN (Serial Number) BA25346 (Top analyzer) and SN BA25347 (Bottom analyzer). 2. A review of the Hematology calibration records revealed the following: A) 09/07/2018 at 1:14 PM: Calibration on the "Top" AcT diff 2 analyzer B) 03/05/2019 at 3:52 PM: Calibration on the "Bottom" AcT diff 2 analyzer C) 03/05/2019 at 5:23 PM: Calibration on the "Top" AcT diff 2 analyzer D) 09/16/2019 at 4:44 PM: Calibration on the "Bottom" AcT diff 2 analyzer E) 09/24/2019 at 3:24 PM: Calibration on the "Top" AcT diff 2 analyzer F) 03/17 /2020 at 10:06 AM: Calibration on the "Bottom" AcT diff 2 analyzer G) 03/17/2020 at 3:00 PM: Calibration on the "Top" AcT diff 2 analyzer H) 06/17/2020 at 3:20 PM: Calibration on the "Bottom" AcT diff 2 analyzer I) 07/23/2020 at 2:02 PM: Calibration on the "Top" AcT diff 2 analyzer J) 09/28/2020 at 2:15 PM: Calibration on the "Bottom" AcT diff 2 analyzer 3. A review of the QC records for the above dates revealed QC was only performed in the morning at approximately 7:00 AM each day. 4. A review of the Coulter AcT diff 2 Analyzer Operator's Guide, under the CALIBRATION section on page 5-18 revealed, "...17. Verify calibration by running 4C PLUS Cell Control. ..." 5. A review of the patient logs revealed patient CBC's were performed and results reported on five calibration days, as follows: A) 03/05 /2019 4:00 - 4:22 PM: 5 patient CBC's were run on the "Bottom" AcT diff 2 analyzer B) 09/24/2019 3:31 - 3:37 PM: 2 patient CBC's were run on the "Top" AcT diff 2 analyzer C) 03/17/2020 11:58 AM - 2:38 PM: 14 patient CBC's were run on the "Bottom" AcT diff 2 analyzer D) 7/23/2020 at 2:13 PM: 1 patient CBC was run on the "Top" AcT diff 2 analyzer E) 9/28/2020 2:25 - 2:52 PM: 3 patient CBC's were run on the "Bottom" AcT diff 2 analyzer There was no documentation of QC performance after the calibrations and before the patient CBC testing. 6. During an interview on 1/6 /2020 at 1:15 PM, Testing Personnel #1 confirmed the laboratory had not performed QC after the calibrations on the above dates, stating QC was not run until the following morning. SURVEYOR ID #32558 Licensure and Certification Surveyor