Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D1050230	12/07/2022
Name of Provider or Supplier	**Street Address, City, State**	
Vanderbilt Health & Williamson Medical Center	3098 Campbell Station Parkway Ste 100, Spring Hill, 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
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 the laboratory procedure manual, quality control (QC) records, the laboratory's quality assessment (QA) plan, monthly quality assessment records, patient test report, and interview with technical consultants, the laboratory failed to have a effective quality assessment process in place to detect and correct problems with quality control limits in 2022, resulting in the use of incorrect Complete Blood Count (CBC) QC limits from approximately 09 /02/22 to 10/19/22 (two of fifteen lots reviewed) with approximately 86 patients reported during the period. The findings include: 1. Observation of the laboratory on 12/07/22 at 11:45 am revealed the Sysmex XP 300 (serial # A9111) instrument in use for patient CBC testing. 2. Review of the laboratory procedure titled "WIC Laboratory Sysmex XP-300 Procedure" revealed the laboratory enters the quality control ranges for the Sysmex XP-300 by scanning the manufacturer's package insert sheet. 3. Review of CBC QC lot numbers 0336, 1054, 1222, 2025, and 2193 revealed the following: Each parent lot contains three levels (ex. 2193-0710, 2193-0711, and 2193-0712) for a total of fifteen lots. Lot number 2193, levels 0710 and 0711 did not have QC ranges that matched the manufacturer stated limits from approximately 09/02/22 to 10/19/22 for the white blood cell analyte. Manufacturer range for 2193-0710 WBC = 2.7 - 3.7 th/uL, laboratory range = 2.5 - 4.1 th/uL. Manufacturer range for 2193-0711 WBC = 6.6 - 8.0 th/uL, laboratory range = 6.7 - 8.3 th/uL. 4. Review of the

	laboratory QA plan revealed that the laboratory would evaluate the entire testing process, identify and correct problems. The QA plan also stated that quality control ranges are determined by the manufacturer of the complete blood cell count (CBC) controls. 5. Review of the laboratory's monthly QA documentation for the months of September and October 2022 revealed no indication that the incorrect QC limits were detected or corrective action performed. 6. Review of patient number CSN # 1970240527353 revealed CBC reported on 10/19/22 when the incorrect quality control limits were in use. 7. Interview with technical consultant numbers one and two on 12/07/22 at 4 pm confirmed the laboratory's quality assessment process was ineffective at detecting and correcting problems with quality control limits in 2022. They further stated approximately 86 patients were reported during the period when the incorrect limits were in use.