Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0904149	11/16/2023
Name of Provider or Supplier	**Street Address, City, State**	
Meigs County Primary Care Center	305 River Rd, Decatur, 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
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: Based on observation of the laboratory, review of Horiba ABX Micros 60 user's manual, laboratory environmental records (04.2023 and 05.2023), and confirmed in interview, the laboratory failed to ensure room temperatures were within operating specifications for the Horiba ABX Micros 60 Complete Blood Count (CBC) instrument for two of two months reviewed. Findings included: 1. Observation of the laboratory on 11.16.2023 at 9:30 a.m. revealed a Horiba ABX Micros 60 (serial number 206CS91668) Complete Blood Count (CBC) instrument in use for patient testing. 2. Review of the Horiba ABX Micros 60 user's manual stated the following in the section titled "Humidity/temperature conditions": "The ABX Micros 60 must operate between temperatures of 18 to 32C (65 to 90F)" 3. Review of the laboratory environmental logs (04.2023 and 05.2023) titled "Daily, Weekly, Monthly, Quality Assurance Log" revealed the laboratory utilized a room temperature range of 15-30C /60-85F. The temperature range used by the laboratory did not correspond to manufacturer's specified acceptable temperature range of 18 to 32C (65 to 90F). 4. Review of laboratory environmental records (04.2023 and 05.2023) revealed the following days when the room temperatures were NOT within manufacturer's operating specifications of 18 to 32C (65 to 90F): 04.04.2023: 41C 04.05.2023: 42C 04.06.2023: 44C 04.07.2023: 42C 04.10.2023: 37C 04.11.2023: 36C 04.12.2023: 35C

	04.13.2023: 35C 04.14.2023: 40C 04.17.2023: 40C 04.18.2023: 35C 04.19.2023: 38C 04.20.2023: 38C 04.21.2023: 37C 04.24.2023: 35C 04.25.2023: 33C 04.26.2023: 37C 04.27.2023: 35C 05.01.2023: 40C 05.02.2023: 38C 05.03.2023: 35C 05.04.2023: 33C 05.05.2023: 35C 05.08.2023: 48C 05.09.2023: 17C The laboratory failed to ensure acceptable room temperatures were within operating specifications for the Horiba ABX Micros 60. 5. An interview on 11.16.2023 at 12:45 p.m. with the Quality Coordinator confirmed the above findings. Word Key: C=Celsius F=Fahrenheit
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of final patient test reports, review of test system records, and staff interview, the laboratory failed to verify the reference ranges that were in use at the time of the survey (11.16.2023) for complete blood count (CBC) patient testing. The findings include: 1. Observation of the laboratory on 11.16.2023 at 9:30 a.m. revealed a Horiba ABX Micros 60 instrument (serial number 206CS91668) in use for CBC patient testing. 2. Review of four final patient test reports (two male patients and two female patients) revealed the following CBC analyte reference ranges in use for patient evaluation: Male -White Blood Cell count (WBC): 4-10.5 -Red Blood Cell count (RBC): 4.1-5.6 -Hemoglobin (HGB): 12.5-17 -Hematocrit (HCT): 36-50 -Platelet count (PLT): 140-415 -Mean corpuscular volume (MCV): 80-98 -Mean corpuscular hemoglobin (MCH): 27-34 -Mean corpuscular hemoglobin concentration (MCHC): 32-36 -Red cell distribution width (RDW): 11.7-15 -Absolute granulocyte count (GRA#): 1.8-7.8 -Relative granulocyte count (GRA%): 40-74 -Absolute lymphocyte count (LYM#): 0.7 - 4.5 -Relative lymphocyte count (LYM%): 14-46 -Absolute monocyte count (MON#): 0.1-1 -Relative monocyte count (MON%): 4-13 Female -White Blood Cell count (WBC): 4-10.5 -Red Blood Cell count (RBC): 3.8-5.1 -Hemoglobin (HGB): 11.5-15 -Hematocrit (HCT): 34-44 -Platelet count (PLT): 140-415 -Mean corpuscular volume (MCV): 80-98 -Mean corpuscular hemoglobin (MCH): 27-34 -Mean corpuscular hemoglobin concentration (MCHC): 32-36 -Red cell distribution width (RDW): 11.7-15 -Absolute granulocyte count (GRA#): 1.8-7.8 -Relative granulocyte count (GRA%): 40-74 -Absolute lymphocyte count (LYM#): 0.7-4.5 -Relative lymphocyte count (LYM%): 14-46 -Absolute monocyte count (MON#): 0.1-1 -Relative monocyte count (MON%): 4-13 3. Review of system records for CBC testing revealed no normal range validation of the reference intervals that were in use for evaluating the laboratory's patient test results. 4. Interview with the Quality Coordinator on 11.16.2023 at 12:45 p.m. confirmed there was no documentation of validation of the reference ranges that were in use for patient evaluation with an estimated annual testing volume of 2304 CBC test results.