

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0726627	(X3) Date Survey Completed 12/03/2020
Name of Provider or Supplier Pediatric First, Pc	Street Address, City, State 1049 N Houston Rd, Warner Robins, GA	
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
D0000	A Clinical Laboratory Improvement Amendments (CLIA) Recertification survey was completed on December 3, 2020. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on the review of the Temperature Charts/Department of Public Health (DPH) Refrigerator and Freezer charts, and staff interview the laboratory failed to document the room temp and humidity as required by the manufacturer for the Cell-Dyn Emerald, hematology analyzer. Findings: 1. Based on the Operator Manual for the Abbott Cell Dyn Emerald, the manufacturer states that the relative humidity should be 80% Maximum, and room temperature up to 90 degrees F, or 32 degrees C. The laboratory did not have a log to document the room temperature and humidity. 2. Based on review of the DPH temp charts, the laboratory documented the room temp from January 2019 to March 2019 across the top of the DPH temp chart, after March 2019 there was no more room temps documented for 2019, and no Humidity documented for 2019. In 2020, there was no room temps or humidity documented. 3. Interview with the office manager, in the back Doctor's office on December 3, 2020, at approximately 1 pm, confirmed that the laboratory did not have a log for</p>

documenting the room temperature and Humidity in the laboratory, and that after March 2019 there was no room temps and humidly documented for the rest of 2019 and all of 2020.