Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	25D2173851	07/13/2021
Name of Provider or Supplier	**Street Address, City, State**	
Phillips Pediatrics Llc	2682 W Oxford Lp Ste 130, Oxford, MS	

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
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: Based on interview with the Laboratory Director and testing personnel (TP) #2 as listed on the Centers For Medicaid & Medicare Services (CMS) 209 form on 7/13/21 at 4:30 p.m., review of 1 Complete Blood Count (CBC) final report, the patient laboratory master testing log and the laboratory labeling policy, the laboratory failed to follow their policy to ensure positive identification of the patient specimen from the time of collection through testing and reporting for CBC results. Findings include: 1. The laboratory's labeling policy states specimens will be labeled with the patient name and DOB (date of birth) or chart number. 2. Interview with Laboratory Director and TP #2 indicated that TP routinely collect patient blood specimens in microtubes for CBC's and go directly to the lab to perform testing without labeling the sample. 3. Observation of 1 of 1 patient CBC reports revealed that the patient name and chart number (PCC #) were printed on the CBC report. This report was scanned into the clinic Laboratory Information System (LIS). 4. Observation of the patient testing master log in the laboratory has the date, chart number (PCC #), tests performed checked and TP's initials. Patient names are not recorded on the log. 5. Interview with the Laboratory Director and TP #2 at 4:30 p.m. on 7/13/21 indicated that TP routinely test unlabeled patient specimens for CBC. 6. This process does not ensure positive identification of a patient's specimen from the time of collection through reporting of results.
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 review of laboratory records since the Abbott Cell-Dyn Emerald installation on 8/26/20 and confirmation with the Laboratory Director (LD), Technical Consultant (TC) and testing personnel (TP) #1 at 4:00 p.m. on 7/13/21, the laboratory failed to monitor and document the room temperature for the laboratory where hematology testing was performed. Findings include: 1. Observation of the laboratory room where hematology testing was performed revealed no thermometer to monitor the room temperature for optimal performance of the Cell-Dyn Emerald hematology analyzer. 2. No room temperature logs were available for review. 3. Cell-Dyn Emerald manufacturer's instructions require: a) The Cell-Dyn Emerald reagent, lyse and detergent should be stored at a temperature range of 18 to 32 degrees Celsius (C). b) The Cell-Dyn Emerald hematology analyzer instrument operating specifications require a room temperature of 18 to 32 degrees C. c) The Cell-Dyn quality control and calibration materials must be allowed to come to room temperature before testing. 4. An interview with the Laboratory Director, Technical Consultant and TP #1 at 4:00 p. m. on the day of survey confirmed no room temperatures were being monitored and documented.