Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0300416	01/14/2020
Name of Provider or Supplier	**Street Address, City, State**	
Bbh Primary Care Network	803 North Street, Talladega, 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
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 a review of the room temperature logs, a lack of room temperature and humidity records after April 2019, a review of environmental requirements for the Abbott Cell Dyn Emerald Hematology analyzer, and an interview with the Technical Consultant and the Testing Personnel, the surveyor determined the laboratory failed to monitor and document room temperature and humidity in the area of operation for the last eight and a half months. The findings include: 1. A review of the Abbott Cell Dyn Emerald Operator's Manual on page 2-4 (viewed by the surveyor on the Abbott website) revealed: "Installation Environment The following are environmental requirements: ... Temperature range: 64 - 90 degrees F (Fahrenheit) ... Maximum relative humidity 80% (percent) for temperatures up 90 degrees F". 2. A review of the 2018-2020 environmental logs revealed the testing personnel had recorded room temperature (acceptable range: 65-75 degrees F), humidity (acceptable ranges: less than 70%), and refrigerator temperatures on a monthly chart until April 2019. Then in May 2019 the laboratory began using a vaccine refrigerator temperature log each day of patient testing, however, the records did not include the temperature and humidity in the room where the Emerald was operated from May 2019 thru the day of the survey. 3. During an interview on 1/14/2020 at 12:40 PM, the Testing Personnel confirmed she had no longer recorded room temperature and humidity after April

	2019 because it was not on the new form. The Technical Consultant then explained TPR (the hospital Quality Assurance entity) had required the facilities to use the vaccine refrigerator temperature log. However, the Technical Consultant had failed to ensure the testing personnel continued to monitor and document room temperature and humidity, as per the manufacturer's instructions.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on a review of a patient results report and interviews with the Technical Consultant and the Testing Personnel, the laboratory failed to ensure the correct name and address of the laboratory performing the testing, and the units of measurement were included on the report. The findings include: 1. On 1/14/2020 at 2:10 PM, the surveyor reviewed the post-analytical process in the facility. Upon the surveyor's request, the Testing Personnel printed a final report from Copia with results for a CBC (Complete Blood Count) she had performed earlier in the day. 2. A review of the Laboratory Report revealed the laboratory name, address, and CLIA number (#) did not belong to this facility (BBH Primary and Specialty Care). The report also failed to include the units of measurement for CBC parameters. 3. As the interview continued on 1/14/2020 at 2:15 PM, the surveyor reviewed the report with the Technical Consultant and the Testing Personnel who confirmed the name, address and CLIA # on the report was the facility with whom this laboratory had merged in August 2018. The Technical Consultant further stated she would investigate why the units of measurement were not printing in the "Units" column of the report. SURVEYOR ID #32558 Licensure and Certification Surveyor