Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0686032	12/15/2021
Name of Provider or Supplier	**Street Address, City, State**	
Jackson Hospital & Clinic	4154 Carmichael Road, Montgomery, 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 observations during the entrance tour, a review of temperature/humidity records, a review of the manufacturer's required environmental operating parameters, and interviews with Testing Personnel #1 and the Quality Coordinator, the laboratory failed to monitor and document room humidity for fifteen months in two Lab Rooms where patient tests were performed on the Bilirubinometer and Hematology analyzers. The findings include: 1. During the entrance tour on 12/15/2021 at approximately 9: 00 AM, the surveyor noted the room temperature monitoring device did not include a hygrometer to monitor humidity in Lab Room 1 (where the Beckman Coulter DxH 520 was located) or Lab Room 2 (where the Reichert Bilirubinometer was located). The surveyor asked Testing Personnel #1 if the laboratory monitored room humidity; Testing Personnel #1 stated she was told this was not required. 2. A review of the temperature/humidity records revealed the laboratory began using new logs without a column to record humidity in September 2020; humidity monitoring in Lab Room 1 and 2 was not documented from September 2020 until the day of the survey (9/15 /2021). 3. A review of the "Beckman Coulter DxH 500 Series Instructions for Use Manual" (in the System Overview section), at the bottom of page 1-7 revealed, "... Humidity The instrument meets performance claims when operated at a maximum of 80% relative humidity (non-condensing) at 32 degrees C [Celsius] (89.6 degrees F

	[Fahrenheit])." 4. A review of the operating requirements for the Reichert Unistat Bilirubinometer on page 8 in the Operator's Manual revealed, "RH [Relative Humidity] 80% up to 31 degrees C decreasing linearity to 50% RH at 40 degrees C..." 5. During an interview on 12/15/2021 at 2:53 PM the surveyor reviewed the above manufacturer's requirements with the Quality Coordinator, Technical Consultant #1 and Testing Personnel #1, and asked why the laboratory had ceased monitoring humidity in September 2020. The Quality Coordinator stated humidity was not monitored in the other laboratories she oversaw, and she had implemented use of the new temperature log for the sake of uniformity; however she had not realized monitoring humidity was required to ensure the analyzers were operated within the manufacturer's specifications. .
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 reviews of patient test reports and an interview with the Quality Coordinator, Technical Consultant #1 and Testing Personnel #1, the laboratory failed to ensure patient reports included all required parameters on two of three reports reviewed. The findings include: 1. On 12/15/2021 at 2:30 PM, the surveyor reviewed the post-analytical process in the facility. Upon the surveyor's request, the Technical Consultant and Testing Personnel #1 provided three final patient reports with CBC (Complete Blood Count), Total Bilirubin, and Throat Culture results from the Athena EMR (Electronic Medical Record). Upon review, the surveyor noted there were no units of measurement for the CBC parameters or the Total Bilirubin results on two of the reports. 2. In an interview on 12/15/2021 at 2:40 PM, the surveyor reviewed the reports with the Quality Coordinator, Technical Consultant #1 and Testing Personnel #1 who confirmed the above noted findings. SURVEYOR ID #32558 Licensure and Certification Surveyor