Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D2104538	07/20/2022
Name of Provider or Supplier	**Street Address, City, State**	
Jackson Hospital & Clinic, Inc	2175 Us Hwy 31 N, Deatsville, 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 reviews of the 2019-2022 temperature records, the Beckman Coulter AcT diff 2 Complete Blood Count (CBC) Hematology analyzer Users Manual, the storage requirements for Coulter 4C-ES Cell Controls, the Policy and Procedures Manual, and an interview with the Laboratory Manager of the main hospital, the laboratory failed to monitor and document environmental parameters to ensure: 1) the Hematology analyzer was operated within the manufacturer's specifications for temperature and humidity, and 2) the Hematology quality control (QC) was stored as per the manufacturer's temperature requirements. The surveyor noted 10 (May 2021 through February 2022) out of 34 months (October 2019 through July 2022) when the laboratory failed to monitor and record room temperature and humidity, and 13 out of 34 days (during March and April 2022) when QC refrigerator temperatures were not documented. The findings include: 1. A review of the 2019-2022 environmental records revealed the following: A. 2021 May through December: no documentation of room temperature and humidity B. 2022 January and February: no documentation of room temperature and humidity C. 2022 March: no documentation of the QC refrigerator temperatures 7 out of 18 days D. 2022 April: no documentation of the QC refrigerator temperatures 6 out of 16 days 2. A review of the Beckman Coulter AcT diff 2 Hematology analyzer Users Manual on page 1-2 "Preinstallation Checks"

	revealed, "... Keep room temperature between 16 degrees and 35 degrees C [Celsius] (61 degrees and 95 degrees F [Fahrenheit]) and humidity to between 20 and 85 percent...". 3. A review of the packaging for Coulter 4C-ES Cell Controls for CBCs revealed storage requirements of 2-8 degrees C. 4. A review of the policy and procedure manual revealed the following: A. Page 2, "The AcT diff 2 analyzer operates at an ambient temperature of 16-35 degrees Celsius and at a humidity of less than 85 percent...". B. Page 6, "The controls must be stored at 2-8 degrees Celsius when not in use...". 5. During an interview on July 20, 2022, at 12:12 PM, the Manager confirmed the above findings.
D6017	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(ii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(ii) Ensure that results are returned within the timeframes established by the proficiency testing program. This STANDARD is not met as evidenced by: Based on a review of the API (American Proficiency Institute) proficiency testing (PT) records, and an interview with the Laboratory Manager of the main hospital, the Laboratory Director failed to ensure results were submitted before the PT provider's cutoff date. This affected one of three 2021 API PT surveys. The findings include: 1. A review of the CMS (Center for Medicare and Medicaid Services) CASPER Report 0096D revealed the laboratory received a 0% score for the third survey event in 2021, due to "Failure to Participate". 2. A review of the API PT records for the 2021 Event #3 Hematology survey revealed the survey samples were shipped on 11/1/2021, however the survey testing was not performed until 1/17/2022. The laboratory had not kept a record of the required submission date for Event 3-2021, however the surveyor noted third event surveys performed in 2019 and 2020 were due in late November. 3. A review of the investigation on the corrective action record revealed, "samples were not ran, samples were placed in fridge and were overlooked and testing not performed ...". 4. During an interview on July 20, 2022, at 10:43 AM, the Manager confirmed the API Event 3-2021 survey results were not submitted before the required cut-off date. SURVEYOR ID#32558 Licensure and Certification Surveyor