

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D1048892	(X3) Date Survey Completed 01/16/2020
Name of Provider or Supplier Etowah Pediatrics	Street Address, City, State 170 Independent Drive, Rainbow City, 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	<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 a review of the environmental logs, and an interview with Testing Personnel (TP) #1, the surveyor determined the laboratory failed to monitor and document room humidity 27 days of patient testing from September through December 2019. The findings include: 1. A review of the 2017-2019 environmental logs revealed the testing personnel had recorded room temperature (acceptable range: 61-95 degrees F [Fahrenheit]), humidity (acceptable ranges: 20-85%), and refrigerator temperatures on a monthly chart until August 2019. Then in September 2019 the laboratory began using a vaccine refrigerator temperature log each day of patient testing. The chart included space to record room temperature, but no dedicated space for humidity. Some of the testing personnel continued to write in the humidity under the room temperature entry, however the surveyor noted 27 days when the laboratory failed to monitor and record humidity: A) on September 18, 20, 24, 25, 26, 27 and 30, 2019 B) on October 1, 2, 3, 4, 9, 18, 21 and 22, 2019 C) on November 1, 7, 13, 14, 19, 20 and 22, 2019 D) on December 3, 6, 18, 20 and 30, 2019 The surveyor further noted the acceptable ranges for room temperature and humidity were not specified on the vaccine refrigerator temperature logs. 2. During an interview on 1/16/2020 at 1:15 PM, the surveyor asked why the laboratory had switched to the new temperature logs. TP replied the "State" had given the facility the chart and required its use for</p>

monitoring any refrigerator with vaccines. The surveyor explained this was a requirement of another agency, not CLIA. The laboratory must ensure the testing personnel continued to monitor and document room temperature and humidity where the AcT diff 2 Hematology analyzer was operated, as per Beckman Coulter's specifications. .

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 records and an interview with the Laboratory Director, the surveyor determined the Laboratory Director failed to ensure Hematology results for one of three 2019 surveys were submitted within the timeframes specified by the proficiency testing program. The findings include: 1. A review of the results from the 2019-Event #1 Hematology survey revealed 0% (percent) scores for all parameters due to failure to participate. 2. A review of the records revealed the survey results were due by 3/29/2019, however the instrument printouts for the survey samples were dated 4/1/2019. 3. During an interview on 1/16/2020 at 10:50 AM, the Laboratory Director confirmed the laboratory had missed the submission cutoff date for the 2019-Event #1 survey.
SURVEYOR ID# 32558 Licensure and Certification Surveyor