

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D0892637	(X3) Date Survey Completed 07/23/2019
Name of Provider or Supplier Pediatric Care Center	Street Address, City, State 304 East 4th Street, Anniston, 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 room temperature logs, a lack of humidity records, a review of environmental requirements for the Abbott Cell Dyn Emerald Hematology analyzer, and an interview with Technical Consultant, the surveyor determined the laboratory failed to: 1) establish acceptable room temperature ranges as per manufacturer's requirements, and 2) monitor and document room humidity in the area of operation since the previous survey on 7/13/2017. The findings include: 1. A review of the Abbott Cell Dyn Emerald Operator's Manual on page 2-4 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 2017-2019 temperature logs revealed the testing personnel recorded room temperature at the bottom of a vaccine refrigerator temperature log each day of patient testing, however no acceptable ranges for room temperature were specified. The records did not include any documentation of room humidity in the room where the Emerald was operated from July 2017 thru July 2019. 3. During an interview on 7/23/2019 at 1:35 PM, the Technical Consultant confirmed the above noted findings, stating the testing personnel had failed to utilize the appropriate form to record environmental parameters. .</p>

D5481

CONTROL PROCEDURES

CFR(s): 493.1256(f)(g)

(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on reviews of the Hematology quality control (QC) records and the patient logs, and interviews with the Technical Consultant, the laboratory failed to ensure at least two levels of quality control were performed and acceptable, prior to analyzing patient specimens and reporting the results on two days in 2018. The findings include:

1. A review of the QC records for the Abbott Cell Dyn Emerald Hematology analyzer revealed the following: A) 3/07/2018: No Normal or High QC performed (The surveyor noted results in the Low QC file were actually patient results erroneously saved in the wrong file; this observation was confirmed by the Technical Consultant.) B) 9/26/2018: No Low QC performed and the Normal QC was outside acceptable ranges
2. A review of the patient logs revealed seven patient CBCs (Complete Blood Counts) were performed on 3/07/2018, and four CBCs were run on 9/26/2018.
3. During interviews on 7/23/2019 at 2:05 and 3:05 PM, the Technical Consultant reviewed and confirmed the above noted findings.

SURVEYOR ID #32558 Licensure & Certification Surveyor