

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0858472	(X3) Date Survey Completed 03/27/2019
Name of Provider or Supplier Floyd County Health Department	Street Address, City, State 16 East 12th Street, Rome, GA	
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
D0000	A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on March 27, 2019. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
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 equipment maintenance document review and staff interview, the laboratory failed to monitor and document temperature for each day of laboratory testing as required. Findings include: 1. Floyd County maintenance document review revealed the laboratory failed to monitor and document the laboratory refrigerator temperature for January through December of 2018. 2. An interview with the nurse manager in the conference room on 3/27/2019 at approximately 4:00 p.m. confirmed the laboratory refrigerator temperature was not monitored and documented for the aforementioned dates.</p>
D5785	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken</p>

when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met.

This STANDARD is not met as evidenced by:

Based on review of temperature records and staff interviews, the lab failed to document corrective actions when Room Temperature (RT) exceeded acceptable limits. Findings include: 1. Review of Catoosa County temperature records November 2017 revealed RT was out of range (64-86°F) 2 of 30 days without corrective actions documented. 2. Interview with the district nurse manager on 3/27/19 at approximately 3:00 PM in the conference room, confirmed the corrective actions were not documented.

D6053

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

Based on testing personnel (TP) document review and staff interview, the technical consultant (TC) failed to perform a six-month competency on TP as required. Findings include: 1. Paulding County TP document review revealed the TC failed to perform a six-month competency for Staff #4 (Paulding County CMS 209) in 2018. 2. An interview with the Nursing and Clinical Director in a conference room on 3/27/2019 at approximately 5:00 p.m. confirmed the aforementioned TP did not have a competency performed in 2018.

D6070

TESTING PERSONNEL RESPONSIBILITIES

CFR(s): 493.1425(b)(1)

Each individual performing moderate complexity testing must follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results.

This STANDARD is not met as evidenced by:

Based on review of daily log sheets and staff interviews, the laboratory personnel failed to record relative humidity (RH) and/ or room temperature (RT) as specified in the procedure manual. Findings include: 1. Review of the Gordon County RT and RH log sheets revealed: RH not recorded 2 of 30 days in November 2017; RH was not recorded either AM or PM 5 of 30 days in November 2017, 1 of 31 days in May 2018, 1 day of 30 in June 2018, 1 day of 31 in October 2018, and 1 day of 31 in December 2018; RT was not documented PM 4 of 30 days in November 2017, 1 of 31 days in May 2018, 1 day of 30 in June 2018, 1 day of 31 in October 2018, and 1 day of 31 in December 2018. 2. Interview with the district nurse manager of Gordon County on 3/27/19 at approximately 3:00 PM in the conference room confirmed the missed recordings of room temperatures or relative humidity.