

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0707029	(X3) Date Survey Completed 08/24/2023
Name of Provider or Supplier Whitfield County Health Department	Street Address, City, State 800 Professional Blvd, Dalton, 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 recertification survey was performed on August 24, 2023. The facility was found to be NOT in compliance with all applicable CLIA requirements for specialties /subspecialties for 42 CFR.
D5291	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.</p> <p>This STANDARD is not met as evidenced by: Based on review of the quality assessment (QA) monthly reports and interview with the director of nursing (DON), the Whitfield County Adult Health laboratory failed to follow the actions of the QA monthly report. Findings include: 1. Review of the QA report for October 2021 revealed the report was incomplete. The Quality Control (QC) section of the form was blank. 2. Review of the QA report for July 2022 revealed the QC section was marked inappropriately as "Y (yes)". The action was marked that "all required temperatures were taken and recorded appropriately", review of the Lab Temperature/Humidity Log for July 2022 revealed the humidity was out of range (40 - 50 %) 19 of 21 days; therefore, the appropriate response to the action would be "N (no)" and corrective actions needed to be noted. 3. Interview with the DON on 8/24/23 at 12:30 pm in the conference room confirmed the aforementioned findings.</p>
D5523	<p>PARASITOLOGY CFR(s): 493.1264(a)(d)</p> <p>The laboratory must have available a reference collection of slides or photographs</p>

and, if available, gross specimens for identification of parasites and use these references in the laboratory for appropriate comparison with diagnostic specimens. (d) The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:

Based on review of the quality control (QC) document review and interview with the director of nursing (DON), the laboratory failed to document QC on potassium hydroxide (KOH) and parasitology slides. The findings include: 1. No QC documents were available to review on KOH or parasitology slides at the time of survey for 8 of 8 locations. 2. Interview with the DON on 08/24/23 at 11:30 AM in the conference room, confirmed controls were not documented on KOH or parasitology slides.

D5781

CORRECTIVE ACTIONS

CFR(s): 493.1282(b)(1)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

Based on review of relative humidity (RH) records and interview with the director of nursing (DON), the lab failed to document corrective actions when RH exceeded acceptable limits or was not documented. Findings include: 1. Review of RH logs revealed: Cherokee - Canton lab failed to record RH for the month of January 2022 Cherokee- Woodstock lab failed to record RH for the months of October 2021 and January 2022 No corrective actions were documented for the failure to record the RH. 2. Review of Whitfield County Adult Health lab RH logs revealed RH was out of range 19 of 21 days without corrective action documented. 2. Interview with the DON on 08/29/23 at 12:44 PM in the conference room, confirmed the corrective actions were not documented.