

<p><b>Statement of Deficiencies</b></p>	<p><b>(X1) Provider/Supplier/CLIA Identification Number</b></p> <p>34D0865330</p>	<p><b>(X3) Date Survey Completed</b></p> <p>12/17/2024</p>
<p><b>Name of Provider or Supplier</b></p> <p>North Carolina County Health Department Area B</p>	<p><b>Street Address, City, State</b></p> <p>Rockingham County Health Department, Wentworth, NC</p>	
<p>For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.</p>		

<p><b>(X4) ID Prefix Tag</b></p>	<p><b>Summary Statement of Deficiencies</b></p>
<p><b>D5417</b></p>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on observation and review of 2024 patient logs 12/17/24, the laboratory failed to discard KOH (potassium hydroxide) that exceeded its expiration date. Approximately 294 patients were tested 4/28/24 to 12/17/24 using the expired KOH. Findings: During a tour of the laboratory at approximately 1:55 p.m., the surveyor observed 1 partially used bottle of EDM3 Potassium Hydroxide 10% in DMSO (lot #2117, expiration date 4/27/24) on the counter beside the microscope, available for use. Review of patient records revealed approximately 294 patient KOH tests were performed by the laboratory from 4/28/24 to 12/17/24 using the expired KOH.</p>
<p><b>D5787</b></p>	<p>TEST RECORDS CFR(s): 493.1283(a)</p> <p>The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s).</p> <p>This STANDARD is not met as evidenced by:</p>

Based on review of the laboratory's policies and procedures and random review of 2023 and 2024 patient logs 12/17/24, the laboratory failed to ensure the GC (Neisseria gonorrhoeae) culture record system included the records and dates of all patient testing performed. Findings: Review of the laboratory's "Gonorrhea Culture Procedure" revealed on pages 4 "... Growth is observed Perform a gram stain on any oxidase positive growth (Refer to Gram Stain Procedure). ... " On page 5, the procedure specified reporting patient GC culture results as "Found" on the patient requisition if oxidase is positive and Gram stain shows Gram negative diplococci. The procedure also included instructions for recording specimen site, growth, oxidase, Gram stain, and final results on the "GC Patient Log". Random review of 2023 and 2024 patient GC culture logs revealed Gram stain results were not documented on the following dates when culture growth was documented as oxidase positive: 1. 2/27/23 - 1 patient 2. 3/1/23 - 1 patient 3. 8/27/23 - 1 patient 4. 4/25/24 - 1 patient