

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  34D0692719	<b>(X3) Date Survey Completed</b>  02/03/2022
<b>Name of Provider or Supplier</b>  Cleveland County Health Department	<b>Street Address, City, State</b>  Cleveland County Public Health Center, Shelby, NC	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D3031</b>	<p><b>RETENTION REQUIREMENTS</b> CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on review of 2020 and 2021 QC(quality control) records and the absence of documentation 2/3/22, the laboratory failed to retain all required DCA Vantage Microalbumin and Creatinine quality control records. Findings: Review of 2020 and 2021 DCA Vantage Microalbumin and Creatinine QC records revealed the laboratory failed to retain copies of the Siemens DCA Systems Microalbumin/Creatinine Control Assay cards with the quality control material acceptable ranges and expiration dates for the following lot numbers: 1. Microalbumin/Creatinine low/high control lot # 0055, unknown expiration date; 2. Microalbumin/Creatinine low/high control lot # 0056, expiration date 9/21(obtained during survey from manufacturer); 3. Microalbumin/Creatinine low/high control lot # 0057, expiration date 3/22(obtained during survey from manufacturer); 4. Microalbumin/Creatinine low/high control lot # 0059, expiration date 1/23(obtained during survey from manufacturer).</p>
<b>D5417</b>	<p><b>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT</b> 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:</p>

Based on observation and review of gram stain QC(quality control) and patient records 2/3/22,the laboratory failed to discard gram stain reagent that had exceeded the expiration date and was used for patient testing. Findings: During tour of laboratory at approximately 9:20 am, the surveyor observed one bottle of BD BBL Gram Crystal Violet reagent,( lot #0140192, expiration date: 12/31/21), located in the gram stain area and in use. Review of gram stain QC records revealed QC was performed weekly from 1/5/22 to 2/2/22 with the expired Gram Crystal Violet reagent. Review of patient records revealed approximately 15 patients were tested with the expired Gram Crystal Violet reagent from 1/3/22 to 1/26/22.