

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  11D2079553	<b>(X3) Date Survey Completed</b>  09/14/2021
<b>Name of Provider or Supplier</b>  Wellstar Urgent Care Woodstock	<b>Street Address, City, State</b>  12201 Highway 92, Suite D, Woodstock, GA	
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>D0000</b>	An initial Clinical Laboratory Improvement Amendments (CLIA) survey was completed on September 14, 2021. The laboratory was not in compliance with all applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
<b>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: A review of the procedure manual and an interview with the laboratory coordinator, it was determined that the laboratory failed to have a comprehensive competency assessment policy specific to the Abbott I-Stat 1 Chemistry Analyzer for 2020 and 2021. Findings include: 1.) Testing Personnel (TP) records review revealed competency assessment was performed on TPs # 1 - 5 (CMS 209) in 2020 and 2021, but was not specific to the Abbott I-Stat 1 Chemistry Analyzer. 2.) Interviews with the laboratory coordinator and office manager confirmed the findings on September 14, 2021 at approximately 12:50 pm in the break room that the laboratory failed to have competency assessment specific to the Abbott I-Stat 1 Chemistry Analyzer.</p>
<b>D6049</b>	<p><b>TECHNICAL CONSULTANT RESPONSIBILITIES</b> CFR(s): 493.1413(b)(8)(iii)</p> <p>The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.</p>

This STANDARD is not met as evidenced by:

Based on review of the laboratory's maintenance records and interviews with the laboratory coordinator, the Technical Consultant (TC) failed to perform his duties appropriately as required by Clinical Laboratory Improvement Amendments (CLIA) in 2020. The findings include: 1. Review of maintenance logs including refrigerator log, revealed the refrigerator temperatures were out of range or recorded wrongly from February 3rd 2020 to December 31st 2020. These logs were actually reviewed and signed by the Technical Consultant (TC). 2. An interview with the laboratory coordinator and office manager on September 14, 2021 at approximately 1:00 pm in the break room confirmed the refrigerator temperatures were out of range or recorded wrongly from February to December 2020.