

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  11D2231396	<b>(X3) Date Survey Completed</b>  02/05/2026
<b>Name of Provider or Supplier</b>  Duluth Urgent Care	<b>Street Address, City, State</b>  2320 Peachtree Industrial Boulevard, Suite 101, Duluth, 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 onsite Complaint survey was completed on February 05, 2026, to investigate complaint intake number GA22026761. The allegations were partially substantiated. The following deficiencies were cited:
<b>D1001</b>	<p><b>CERTIFICATE OF WAIVER TESTS</b> CFR(s): 493.15(e)</p> <p>493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.</p> <p>This STANDARD is not met as evidenced by: Findings: 1. Observations during the laboratory tour on 02/05/2026 at approximately 10:15 AM revealed there were no SOPs (Standard Operating Procedures) manuals or modified manufacturer's instructions available to guide testing personnel for the following waived tests: Waived CBCs performed on Sysmex XW-100 analyzer. Dip stick urinalysis and urine HCG pregnancy tests. Healgen rapid strep, covid-19 antigen and Flu A+B Ag combo tests. Helicobacter Pylori and Mono tests by Sekisui Diagnostics LLC. Basic metabolic chemistry performed on Piccolo Express Abaxis. 2. Maintenance and documents review on 02/05/2026 at approximately 11:00 AM revealed there were no required daily Quality Control (QC) documentations on all in-house testing in this location from February 2024 through February 05, 2026. 3. No documentations of laboratory's room temperatures, refrigerator temperatures and humidity during daily testing from February 2024 to February 2026 on this location. 4. No policies on specimen collection, handling, transportation and resulting guidelines for testing personnel on this location.as of 02/05/2026. 5. Several test kits were also expired on the day of survey 02/05/2026: Healgen covid-19, Flu A&amp;B rapid Combo tests expired 10/31/2025, Osom Mono tests by Sekisui Diagnostics llc had an expiration date of 09/ 2025. Labcorp model 642 E centrifuge was last calibrated on 03</p>

/28/2019. 6. An interviews with lead MA and staff at approximately 1:55 PM on 02/05 /2026 confirmed the lack of laboratory (SOPs), Quality Control (QC) documentations, refrigerator, room temperature and humidity monitoring, including expired test kits for the aforementioned waived tests from February 2024 through day of survey 02/05 /2026.