

<p>Statement of Deficiencies</p>	<p>(X1) Provider/Supplier/CLIA Identification Number</p> <p>11D2159943</p>	<p>(X3) Date Survey Completed</p> <p>02/05/2026</p>
<p>Name of Provider or Supplier</p> <p>Braselton Urgent Care</p>	<p>Street Address, City, State</p> <p>2620 Old Winder Highway, Suite 300, Braselton, GA</p>	
<p>For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.</p>		

<p>(X4) ID Prefix Tag</p>	<p>Summary Statement of Deficiencies</p>
<p>D0000</p>	<p>An onsite Complaint survey was completed on February 05, 2026, to investigate complaint intake number GA22023021. The allegations were substantiated. The following deficiencies were cited:</p>
<p>D1001</p>	<p>CERTIFICATE OF WAIVER TESTS 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: Based on observation during the laboratory tour and staff interview, the laboratory failed to establish Standard Operating Procedures (SOPs) or modified manufacturer's instructions for all waived tests performed by the Clinic's laboratory as required from February 2024 through February 05, 2026. 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 document review on 02/05/2026, at approximately 11:00 AM, revealed there were no required daily Quality Control (QC) documentations for all in-house testing , from February 2024 through February 05, 2026. 3. There was no documentation of the laboratory's room temperatures, refrigerator temperatures and humidity for the daily testing from February 2024 to February 2026. 4. There were no policies on specimen collection, handling, transportation and resulting guidelines for testing personnel, as</p>

of 02/05/2026, the date of survey. 5. Several test kits were also expired, on the day of survey, 02/05/2026: Healgen covid-19, Flu A&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 03/28/2019. 6. An interview with lead MA and staff , at approximately 11:45 AM, 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.