

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 26D1077619	(X3) Date Survey Completed 04/01/2021
Name of Provider or Supplier Total Access Urgent Care	Street Address, City, State 9556 Manchester Road, Saint Louis, MO	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES 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: Based on review of "Laboratory Personnel Policies" and interview with the laboratory director, the laboratory failed to include a procedure for competency completed remotely by Zoom or FaceTime. Findings: 1. Review of "Laboratory Personnel Policies" did not include competencies could be performed remotely by Zoom or FaceTime. 2. Interview with the laboratory director stated competencies in 2020/2021 were performed by Zoom or FaceTime. 3. Interview with the laboratory director on March 30, 2021 at 10:30 AM confirmed the laboratory's personnel policies failed to include that competency could be performed remotely by Zoom or FaceTime.</p>
D5807	<p>TEST REPORT CFR(s): 493.1291(d)</p> <p>Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.</p> <p>This STANDARD is not met as evidenced by: Based on review of iSTAT procedure manual, iSTAT validation, iSTAT patient report and interview with laboratory director, the laboratory failed to ensure the iSTAT procedure manual reference ranges matched the references ranges on the iSTAT validation and patient report. Findings: 1. Review of the iSTAT procedure manual</p>

showed the reference ranges as: Sodium 138 - 146 mmol/L Potassium 3.5 - 4.9 mmol/L Chloride 98 - 109 mmol/L Glucose 70- 105 mg/dL Ionized Calcium 1.12 - 1.32 mmol/L Creatinine 0.6 - 1.3 mg/dL BUN 8 - 26 mg/dL Hematocrit Female 38 - 46 Male 43 -51 %PCV 2. Review of the iSTAT validation and patient report showed the reference ranges as: Sodium 128 - 145 mmol/L Potassium 3.6 - 5.1 mmol/L Chloride 98 - 108 mmol/L Glucose 73 - 118 mg/dL Ionized Calcium 1.2 - 1.32 mmol/L Creatinine 0.6 - 1.2 mg/dL BUN 7 - 22 mg/dL Hematocrit Female 37 - 47 Male 42 -52 %PCV 3. Interview with laboratory director on March 30, 2021 at 10:30 AM confirmed that the iSTAT procedure reference ranges did not match the iSTAT validation and iSTAT patient report reference ranges.