

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 26D0446211	<b>(X3) Date Survey Completed</b> 04/17/2025
<b>Name of Provider or Supplier</b> Women's And Children's Hospital	<b>Street Address, City, State</b> 404 Keene Street, Columbia, MO	
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>D5807</b>	<p>TEST REPORT CFR(s): 493.1291(d)</p> <p>(d) 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 patient test reports, approved procedure manual and interview with the technical consultant, the laboratory failed to ensure pertinent venous pH normal values as determined by the laboratory were available for interpretation. Two of two selected test reports generated April 17, 2025 included venous pH normal values that differed from those stated in the approved procedure manual. Findings: 1. The difference between normal values included on two selected test reports and those included in the approved procedure manual are as follows: -pH normal values included on test reports (7.31-7.45) -pH normal values stated in the approved procedure manual (7.35-7.45) 2. Interview with the technical consultant on April 17, 2025 at 11:05 AM confirmed the discrepant normal values.</p>
<b>D6013</b>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii)</p> <p>(e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and</p> <p>This STANDARD is not met as evidenced by: Based on review of verification procedures for I-Stat analyzer serial # 404127 on April 17, 2025 and interview with the technical consultant, the laboratory director failed to ensure verification procedures were adequate for the test method. Findings:</p>

1. The laboratory did not have documentation to show the laboratory director evaluated and approved the I-Stat verification procedures for CG8+ cartridges that perform sodium, potassium, calcium, glucose, hematocrit, hemoglobin, pH, pCO<sub>2</sub>, pO<sub>2</sub>, TCO<sub>2</sub>, base excess and sO<sub>2</sub> on the I-Stat analyzer. 2. Interview with the technical consultant on April 17, 2025 at 11:05 AM, confirmed the laboratory director failed to approve verification procedures for tests performed on the I-Stat analyzer.

**D6020**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(5)

(e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;

This STANDARD is not met as evidenced by:  
Based on review of the laboratory's quality assessment (QA) program on April 17, 2025 and interview with the technical consultant, the laboratory director failed to approve the QA program. Findings: 1. The laboratory did not have documentation to show the laboratory director approved the QA program in use. 2. Interview with the technical consultant on April 17, 2025 at 11:05 AM confirmed the QA program did not include approval by the laboratory director.