

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 03D2211250	(X3) Date Survey Completed 10/04/2023
Name of Provider or Supplier Chandler Surgical Center, Plc	Street Address, City, State 600 S Dobson Rd Ste B16, Chandler, AZ	
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
D5301	<p>TEST REQUEST CFR(s): 493.1241(a)</p> <p>The laboratory must have a written or electronic request for patient testing from an authorized person.</p> <p>This STANDARD is not met as evidenced by: Based on lack of test requisition documentation for review and interview with the Technical Consultant (TC-1), the laboratory failed to have a written or electronic request for patient testing for one out of three patient records reviewed during the survey. Findings include: 1. The laboratory began patient testing for Arterial Blood Gases (ABG) on the i-Stat analyzer in August 2023. 2. No written or electronic request for ABG testing was presented for review for one out of three patient records reviewed during the survey (patient ID: 247, tested on 8/23/23). 3. The TC-1 interviewed on October 4, 2023 at 10:35 AM confirmed the laboratory failed to have an electronic or written test requisition for Blood Gas testing for the patient indicated above. 4. The laboratory's reported annual test volume for the specialities of Chemistry and Hematology is 4,100.</p>
D5421	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.</p>

This STANDARD is not met as evidenced by:

Based on review of performance specification documentation for Arterial Blood Gas (ABG), Chem8+ panel, Activated Clotting time (ACT), and Prothrombin Time (PT) testing performed on the i-Stat analyzer and interview with the Technical Consultant (TC-1), the laboratory failed to verify the reportable ranges and the reference ranges prior to reporting patient test results. Findings include: 1. The laboratory uses four test cartridges on the i-Stat analyzer for patient testing. These include: CG4+ (for ABG testing), Chem8+, ACT, and PT/INR cartridges: - The CG4+ cartridge includes the following analytes: Lactate, pH, pCO₂, pO₂, TCO₂, HCO₃, Base Excess (BE) and SO₂. - The Chem8+ cartridge includes the following analytes: Sodium, Potassium, Chloride, Glucose, Ionized Calcium, Urea Nitrogen (BUN), Creatinine, Anion Gap, Hematocrit (HCT) and Hemoglobin (HGB). -The ACT cartridge includes the test: Activated Clotting time (ACT). -The PT/INR cartridge includes the test: Prothrombin time (PT) / International Normalized Ratio (INR). 2. Prior to reporting patient test results on the i-Stat analyzer, the laboratory failed to demonstrate that it can obtain the reportable range and reference range comparable to those established by the manufacturer for each i-Stat test cartridge used by the laboratory for patient testing. 3. TC-1 interviewed on 10/04/23 at 09:50 AM confirmed the laboratory failed to provide evidence of the reportable and reference ranges for the testing listed above. 4. The annual test volume in the specialties of Hematology and Chemistry is 4,100. 5. The laboratory began patient testing using the ACT, PT/INR, and Chem8+ test cartridges in March 2022. The laboratory began using the CG4+ test cartridge for patient testing in August 2023.