

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  13D2114533	<b>(X3) Date Survey Completed</b>  03/20/2019
<b>Name of Provider or Supplier</b>  St Alphonsus Medical Group - South Nampa	<b>Street Address, City, State</b>  215 E Hawaii Ave, Nampa, ID	
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>D2015</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: Based on a proficiency testing (PT) record review and an interview with the laboratory testing personnel, the laboratory director and 1 out of 1 testing personnel failed to sign the attestation statements from the American Proficiency Institute (API) for the analysis of blood gases in all three events in 2018. Findings: 1. An API PT document review revealed the laboratory director and 1 out of 1 testing personnel performing blood gases on the GEM 4000 failed to sign the attestation statements for all three events in 2018. 2. The laboratory performed approximately 50 blood gases in 2018. 3. An interview on March 20, 2019 at 9:15 AM, with the laboratory testing personnel, confirmed the laboratory director and testing personnel failed to sign the PT attestation statements in 2018.</p>
<b>D5413</b>	<p><b>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT</b> CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper</p>

storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:  
Based on a record review and an interview with the laboratory testing personnel, the laboratory failed to monitor and document the room temperature where the GEM 4000 blood gas analyzer was used since the last survey on July 25, 2017. Findings: 1. A record review of temperature logs revealed the laboratory failed to monitor and document the room temperature where the Gem 4000 blood gas analyzer was used to test patient blood gases since the last survey. 2. The laboratory performed approximately 50 blood gases in 2018. 3. An interview on March 20, 2019, at 10:05 AM, with the testing personnel, confirmed the laboratory failed to document the room temperature since the last survey.

**D5445**

**CONTROL PROCEDURES**  
CFR(s): 493.1256(d)(1)(2)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:  
Based on a record review and an interview with the laboratory testing personnel, the laboratory failed to perform quality control at least once each day of patient testing or write an Individualized Quality Control Plan (IQCP) for the analysis of blood gases on the GEM 4000 since the last survey on July 25, 2017. Findings: 1. A review of laboratory documents revealed the laboratory failed to perform quality control at least once each day of patient testing and failed to write and IQCP since the last survey. 2. The laboratory performed approximately 50 blood gases in 2018. 3. An interview on March 20, 2019 at 9:50 AM, with the laboratory testing personnel, confirmed the laboratory failed to perform quality control at least once each day of patient testing or write an IQCP.

**D6021**

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

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:  
Based on a review of the procedure manual and an interview with the laboratory testing personnel, the laboratory director failed to ensure the quality assessment program for the laboratory was established since the last survey on July 25, 2017. Findings: 1. A review of the procedure manual revealed the laboratory director failed to establish and write a policy or procedure for a system to monitor, assess, and correct problems in the preanalytic, general laboratory system, analytic, and post-analytic processes in the laboratory. 2. An interview on March 20, 2019 at 10:15 AM, with the laboratory testing personnel, confirmed the laboratory director failed to establish and write policies and procedures for a system to monitor all quality assessment activities in the laboratory's test performance of blood gases.

**D6046**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:  
Based on a personnel record review and an interview with the laboratory testing personnel, the technical consultant who is also the laboratory director failed to evaluate the competency of 1 out of 1 testing personnel performing the analysis of blood gas on the GEM 4000 since the last survey on July 25, 2017. Findings: 1. A review of personnel documents revealed the technical consultant failed to evaluate the competency for 1 out of 1 testing personnel performing blood gas analysis on the GEM 4000 since the last survey. 2. An interview on March 20, 2019 at 9:20 AM, with the laboratory testing personnel, confirmed the technical consultant failed to perform competency assessments for the testing personnel.