

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  52D0929354	<b>(X3) Date Survey Completed</b>  11/18/2020
<b>Name of Provider or Supplier</b>  Oakleaf Surgical Hospital Llc	<b>Street Address, City, State</b>  1000 Oakleaf Way, Altoona, WI	
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>D2000</b>	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on surveyor review of the federal Certification and Survey Provider Enhanced Reports (CASPER), proficiency testing (PT) records, laboratory records, and interview with the technical consultant, the laboratory did not enroll in PT for blood gas testing in 2019. Findings include: 1. Review of CASPER report 155 'Individual Laboratory Profile' for OakLeaf Surgical Hospital LLC, CLIA number 52D0929354 showed no results for blood gas testing, including the regulated analytes pH (a measure of the hydrogen ion concentration in blood), pO2 (partial pressure of oxygen), and pCO2 (partial pressure of carbon dioxide) in 2019. 2. Review of the American Proficiency Institute (API) 'Comparative Evaluation Forms' for the three Chemistry Core events in 2019 showed no evidence of Blood Gas results submitted to or graded by API for this laboratory. 3. Review of the OakLeaf Surgical Hospital 'Lab Resulted Test Counts' report for January 1, 2019 - December 31, 2019 showed the laboratory reported blood gas results for six patients during 2019. 4. Interview with the technical consultant on November 18, 2020 at 8:15 AM confirmed the laboratory did not enroll in PT for blood gas testing in 2019 and confirmed the laboratory performed patient blood gas testing during 2019.</p>

**D5407**

**PROCEDURE MANUAL**

CFR(s): 493.1251(d)

Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.

This STANDARD is not met as evidenced by:

Based on surveyor review of laboratory procedures and interview with the technical consultant, the current laboratory director has not approved, signed, and dated the procedures and Individualized Quality Control Plan (IQCP) in use in the laboratory. Findings include: 1. Review of the laboratory procedure manuals and IQCP for the iSTAT analyzer show no evidence of review or approval of the procedures by the current laboratory director. 2. Interview with the technical consultant on November 18, 2020 at 1:25 PM confirmed the current laboratory director has not signed and dated the laboratory procedures or IQCP since taking the role of laboratory director in July 2020.

**D5805**

**TEST REPORT**

CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:

Based on surveyor review of test reports for frozen sections and interview with the laboratory manager, the 'Frozen Section Report' for three of three patients reviewed does not include the time the laboratory received the specimen or reported the test result. Findings include: 1. Review of "Frozen Section Report" forms for patients one, two, and three, showed the form includes space to record the time the laboratory received the specimen and reported the results. Two of the three reports (patients two and three) show the laboratory sequentially received and reported three specimens for each patient. The three reports reviewed do not show receipt or report times. 2. Interview with the laboratory manager, staff A, on November 18, 2020 at 2:15 PM confirmed the testing personnel performing the frozen sections did not complete the reports to include the time the laboratory received the specimen or reported results.