Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D0929354	07/21/2022
Name of Provider or Supplier	**Street Address, City, State**	
Oakleaf Surgical Hospital Llc	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.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D3041	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(6) Test reports. Retain or be able to retrieve a copy of the original report (including final, preliminary, and corrected reports) at least 2 years after the date of reporting. (i) In addition, retain immunohematology reports as specified in 21 CFR 606.160(d) (ii) and pathology test reports for at least 10 years after the date of reporting. This STANDARD is not met as evidenced by: Based on surveyor review of patient test reports and interview with the technical consultant, the laboratory was not able to retrieve a copy of the original preliminary frozen section report for one of three patients reviewed. Findings include: 1. Review of pathology and frozen section patient reports showed the laboratory utilizes two forms, one for the preliminary frozen section report to include the time the specimen is received and time the diagnosis is reported to the surgeon from the pathologist. Further review showed the frozen section diagnosis is part of the final pathology report but does not include the time the specimen is received and the time the diagnosis was reported to the surgeon from the pathologist. 2. Review of pathology patient reports showed patient 1 had a frozen section procedure on August 5, 2021. Further review showed no evidence of the preliminary report from the frozen section to include the time the specimen was received and time the diagnosis was reported to the surgeon by the pathologist. 3. Interview with the technical consultant on July 21, 2022 at 2:03 PM confirmed the laboratory was not able to retrieve a copy of the original preliminary frozen section report for one of three patients reviewed.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification

	procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on surveyor review of calibration verification records and interview with the technical consultant, the laboratory did not perform calibration verification every six months for the CHEM8+ test cartridge on the Abbott i-STAT chemistry analyzer in 2021. Findings include: 1. Review of the calibration verification records for the Abbott i-STAT chemistry analyzer showed calibration verification performed on the CHEM8+ test cartridge on June 2, 2021 and June 8, 2022. Further review showed no additional documentation of calibration verification between those dates. 2. Interview with the technical consultant on July 21, 2022 at 2:55 PM confirmed the laboratory did not perform calibration verification every six months for the CHEM8+ test cartridge on the Abbott i-STAT chemistry analyzer in 2021.