Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D0646021	01/14/2020
Name of Provider or Supplier	**Street Address, City, State**	
Oral & Maxillofacial Path Diag & Consultative Serv	1430 John Wesley Gilbert Drive, Gc2164, Augusta, GA	

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
D0000	A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on January 14, 2020. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper 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 maintenance log review and staff interview and staff interview, the laboratory failed to monitor and document humidity as required by the manufacturer. Findings include: 1. Maintenance log review revealed the laboratory failed to monitor humidity in the microscope room and the histology room as recommended by the microscope manufacturer and the fume hood manufacturer for 2018 (March through December), 2019, and 2020 thus far. 2. An interview with the histotech in the microscope room at approximately 3:30 p.m. on 1/14/2020 confirmed the lack of humidity monitoring and documentation for the aforementioned dates.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)

	For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on maintenance document review and staff interview, the laboratory failed to document and perform maintenance as defined by the manufacturer and with the frequency specified by the manufacturer as required. Findings include: 1. Maintenance document review revealed the Olympus microscope in the microscope room was not professionally calibrated in 2018. 2. An interview with the laboratory director in the microscope room on 1/14/2020 at approximately 2:45 p.m. confirmed the lack of Olympus microscope professional calibration in 2018. .