Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D2114365	(X3) Date Survey Completed 08/14/2019
Name of Provider or Supplier American Foot & Leg Specialists, Llc	**Street Address, City, State** 1109 Eagles Landing Pkwy, Stockbridge, 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 August 14, 2019. 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 operator manual & document review, and staff interviews, the laboratory failed to monitor room temperature (RT) or relative humidity (RH) for the Tissue Tek processor as required by the manufacturer. Findings include: 1. Review of the manufacturer operator manual revealed RT should be maintained between 10-40*C, and RH should be between 0-85%. 2. Document review revealed the lab was not monitoring or documenting the RT or RH . 3. Interviews with staff #2 and #3 (CMS 209 form) on 8/14/19 in the stockroom at approximately 1230 PM, confirmed the maintenance was not performed or documented per the procedure manual.
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 observation, document review, and interviews with general supervisors (GS), the lab failed to perform maintenance on the fume hood, refrigerator, freezer, or paraffin holding tank per the procedure manual. Findings include: 1. Observation during the lab tour revealed the Avantik fume hood was validated October 2017 and April 2018. Procedure manual requires every 6 months. 2. Review of maintenance log documents revealed the lab did not perform the filter change monthly on the fume hood. Maintenance was not documented on the refrigerator or freezer June 2018 through September 2018. Maintenance was not documented on the refrigerator, freezer, or the parafin holding tank October 2018 through January 2019. 3. Interviews with staff #2 and #3 (CMS 209 form) on 8/14/19 in the stockroom at approximately 1130 AM, confirmed the maintenance was not performed or documented per the procedure manual.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of temperature records and staff interviews, the lab failed to document corrective actions when the temperature of the paraffin tank exceeded acceptable limits. Findings include: 1. Review of temperature records revealed paraffin tank temperature was out of range each day in July 2019 without corrective actions documented. 2. Interview with staff #2 (CMS 209 form) on 8/14/19 at approximately 1:00 PM in the stock room, confirmed the corrective actions were not documented.