Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D2063166	02/04/2020
Name of Provider or Supplier	**Street Address, City, State**	
Direct Path Services, P C	30200 Telegraph Road Suite 405, Bingham Farms, MI	

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
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: A Based on document review and interview with the Laboratory Director (LD) and the Operations Manager (OM), the laboratory failed to perform and document room temperature and humidity readings for 2 (February 2018 and February 2019) of 2 years. Findings include: 1. Document review revealed a lack of documentation of the room temperature and humidity readings in the main laboratory, the Laboratory Director's office, and the conference room where microscopes are located. 2. Review of the "Olympus BX41" and the "Biological Microscope M Series" instructions revealed the operating environment should be as follows: a. Olympus BX41 - room temperature 5-40 degrees C / 41-104 degrees F with a relative humidity 80% b. M Series - room temperature 0-40 degrees C and a relative humidity of 85%. 3. During the interview on 2/4/2020 at 11:13 am, the LD and OM confirmed the temperature and humidity readings were not performed and documented. B Based on document review and interview with the Laboratory Director (LD) and the Operations Manager (OM), the laboratory failed to perform and document pipette calibrations for 2 (February 2018 and February 2019) of 2 years in use. Findings include: 1. Review of "Diamond Instruction Manual" under the calibration section states "It is recommended to check the calibration as least once a year, for regularly used pipette." 2. Document review revealed a lack of documentation for pipette calibrations for 2 (February 2018 and February 2019) of 2 years. 3. During the interview on 2/4/2020 at 11:20 am, the LD and OM confirmed the pipettes were not calibrated regularly.