Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2080975	10/11/2021
Name of Provider or Supplier	**Street Address, City, State**	
Florida Physician Specialists Llc	710 Lomax St, Jacksonville, FL	

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	At the time of the announced, onsite recertification survey, Florida Physician Specialists was found to not be in compliance with the CLIA laboratory requirements of 42 CFR 493.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on record review and staff interview, the facility failed to have personnel competency assessment performed by a qualified Technical Consultant or Technical Supervisor for 1 of 4 testing personnel reviewed (Testing person D). Findings include: The form titled "Competency Checklist" states "Evaluator: Document by dating and initialing each item at the time of evaluation that employee has shown competency and complete the method of review to include information on specific tests and records reviewed." Review of Personnel Competency assessment records for Testing person D showed annual competency was performed on 2/16/21 by Testing Person C. Testing Person C does not qualify as a Technical Consultant or Technical Supervisor. The interview with Testing Person C on 10/11/21 at 2:30PM confirmed they did not have the requirements to perform Competency Assessment.
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 record review and staff interview, the laboratory failed to document daily laboratory room temperature and humidity for one of three months reviewed (July 2020). The findings include: Review of the document titled "Humidity & Ambient Temperature Chart Accessioning Area" dated July 2020 showed daily temperature and humidty was documented on July 1, 2, 3, 6, 7, 13, 20, 27, 28, 29, 30, and 31. The remaining days (July 8, 9, 10, 14, 15, 16, 17, 21, 22, 23, and 24) had a line drawn down through the column with an arrow at the end. During an interview on 10/11/21 at 12:00PM with Testing Person B, it was confirmed that room temperature was not recorded daily and a line was drawn from the start of the week until weeks end.
D5645	CYTOLOGY CFR(s): 493.1274(d)(3) (d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(3) The laboratory must maintain records of the total number of slides examined by each individual during each 24-hour period and the number of hours spent examining slides in the 24-hour period irrespective of the site or laboratory. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to document and maintain records number of hours spent examining cytology slides during each 24 hour period for two of two years reviewed (2019-2021). Findings include: Review of the laboratory's cytology logs showed that the laboratory failed to have records showing the amount to time spent examining cytology slides during each 24 hour period from August 2019 - September 2021. During an interview on 10/11/14 at 12:20 PM, Testing Person B acknowledged that the laboratory did not have records showing the amount to time spent examining cytology slides.