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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 10D2166854 | (X3) Date Survey Completed 11/06/2019 |
| Name of Provider or Supplier Indian River Pathology Llc | Street Address, City, State 525 Nw Lake Whitney Place Suite 206, Port Saint Lucie, 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 | An initial certification survey was conducted on November 6, 2019. Indian River Pathology LLC clinical laboratory was found not in compliance with 42 CFR 493, requirements for clinical laboratories. |
| D5413 | <p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to record the humidity of the room where testing was performed from 11/6/17 to 11/6/19. Findings: Review of the operations manual for the laboratory's Avantik cryostat noted that the maximum relative humidity should be 60%. A review of the laboratory's logs showed that the laboratory failed to record the humidity of the room where testing was performed. During an interview on 11/6/19 at 3:09 PM, the Histology Technician stated that they did not record the humidity of the laboratory.</p> |