Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2075815	03/02/2018
Name of Provider or Supplier	**Street Address, City, State**	
Dr Prosper Abitbol Pa	801 Meadows Rd Ste 107, Boca Raton, 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
D3001	FACILITIES CFR(s): 493.1101(a)(1) The laboratory must be constructed, arranged, and maintained to ensure the space, ventilation, and utilities necessary for conducting all phases of the testing process. This STANDARD is not met as evidenced by: Based on observation and an interview with the testing person, laboratory failed to provide adequate testing space and sanitary conditions to the tetsing personnel. Findings included: Observation on March 2, 2018 at 11:00AM revealed that; 1) There was no eyewash station in the laboratory. 2) Ladies purses were kept on Tissue Tek processor. 3) Laboratory back door opened inward, across the Tissue Tek, not leaving testing space for testing person. Back door was used by testing personnel and by other laboratory office employees. 4) No sufficient workbench space for test specimens, requisition slips and record log book. During an interview on March 2, 2018 at 12:00 PM, testing person confirmed that; 1) There was no eyewash station in the laboratory. 2) Ladies purses were kept on Tissue Tek processor. 3) Laboratory back door across the Tissue Tek opened inward, not leaving space for testing person. Back door was used by testing personnel and by other laboratory office employees. 4) No sufficient workbench space for test specimens, requisition slips and record log book.
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by:

	Based on observation and an interview with the testing person, laboratory failed to provide the safety and sanitary conditions to the patients and personnel. Findings included: Observation on March 2, 2018 at 11:00AM revealed that; 1) There was no eyewash station in the laboratory. 2) laboratory floor had several loose wooden rectangular tiles. 3) Ladies purses were kept on Tissue Tek processor. 4) Laboratory back door across the Tissue Tek Processor opened inward, leaving no testing space for testing person. Back door was used by testing personnel and by other laboratory office employees. During an interview on March 2, 2018 at 12:00 PM, testing person confirmed that; 1) There was no eyewash station in the laboratory. 2) laboratory floor had several loose wooden rectangular tiles. 3) Ladies purses were kept on Tissue Tek processor. 4) Laboratory back door across the Tissue Tek Processor opened inward, leaving no testing space for testing person. Back door was used by testing personnel and by other laboratory office employees.
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 interview with testing person, laboratory failed to assess the competency of clinical consultant for 2 out of 2 (2016 and 2017) years reviewed. Findings included: Competency record review on March 2, 2018 at 3:15PM revealed no competency evaluations for clinical consultant for the years 2016 and 2017. During an interview on March 2, 2018 at 3:30 PM, testing person confirmed that no competencies were completed on the clinical consultant for the years reviewed.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on observation, record review and the interview with the testing person, laboratory failed to follow their owne procedures for the following areas; - monitor grounding check for the microscope, -monitor the refrigerator temperature, - have the computer key boards in the laboratory in the testing area, Findings included: A) Procedure manual review on March 2, 2018 at 3:45PM revealed that; 1- procedures for grounding check for Olympus microscope to be monitored annually were not followed. 2- procedure regarding Computer keyboards was listed under clean areas, and not to be entered with gloves on; which was not followed. A) there were norecords for Olympus microscope maintenance, that would include annual grounding check. B) Thermco external thermometer to monitor Haier refrigerator temperature did not function to show the monitored or stored temperature. C) Thermco external thermometer was not calibrated after February 26, 2014. D) Known positive quality control blocks for Helicobacter pylori(H pylori) test; Periodic acid Schiff(PAS), Alcian Blue (AB) , stored in Haier refrigerator. E) there was no other thermometer inside Haier refrigerator to monitor the temperature. F) The laboratory specimen

	processing area had a computer and computer keyboard. During an interview on March 2, 2018 at 4:15 PM, testing person confirmed that; (a) there were no records for Olympus microscope maintenance, that would include annual grounding check. (b) at the time of survey, Thermco external thermometer for Haier refrigerator did not show the stored temperatures, as it was supposed to. (c) Thermco external thermometer for Haier refrigerator had calibration date as February 26, 2014, with no other annual calibration dates. (d) Known positive quality control blocks for Helicobacter pylori(H pylori) test; Periodic acid Schiff(PAS), Alcian Blue (AB) , stored in Haier refrigerator. (e) there was no thermometer inside the Haier refrigerator to monitor temperature. (f) The laboratory specimen processing area had a computer and computer keyboard.
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 observation, record review and interview the laboratory failed to check and monitor room temperature and humidity from January 2016 to March 2, 2018 for the subspecialty of histopathology and cytology testing. Findings included: On 3/2/18 at 1: 00PM, surveyor did not observe humidity check/ room temperature monitoring device in the laboratory. Instrument maintenance records from January 2016 to March 2, 2018 did not show records of humidity check or room temperature for the subspecialty of histopathology and cytology testing. During an interview on 3/2/18, at 1:15 PM, the testing person confirmed that the laboratory did not monitor the room temperature or humidity from January 2016 to March 2, 2018 for the subspecialty of histopathology and cytology testing. And that there were no previous records from year 2014 or 2015 and no humidity check/ room temperature monitoring device in the laboratory.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on observation and interview, the laboratory had expired reagents. Findings included: Observation on March 2, 2018 at 1:15 PM revealed; 1) Acetone, purified - lot# 1407101, expiration date; 9/9/16. 2) Platinum line xylenes - lot# 1520322, expiration date; 1/18/2018. 3) Acetic acid solution (0.5%) - lot# 31435, expiration date; 2015-12. 4) Hydrochloric acid solution 1.00 Normal- lot # 12119224; expiration date; 7/13/14. 5) Plastic bottle labeled as acetic acid, had date 3/14/14. During an

	interview on March 2, 2018 at 1:30 PM, testing person confirmed that the reagents 1-5 had expired and they were not isolated or labeled as not in use-expired.
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 record review and interview the laboratory failed to perform and record microscope maintenance from January 2016 to March 2, 2018 for the subspecialty of histopathology and cytology testing. Findings included: On 3/2/18 at 2:30PM instrument maintenance log records from January 1, 2016 to March 2, 2018 showed no documentation of microscope maintenance for the subspecialty of histopathology and cytology testing. During an interview on 3/2/18, at 3:30 PM, the testing person confirmed that the laboratory did not perform yearly microscope maintenance from January 2016 to March 2, 2018 for the subspecialty of histopathology and cytology testing. Also, there were no previous records from year 2014 or 2015 for any microscope maintenance.
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on observation, record review and the interview with the testing person, laboratory director failed to be responsible for overall operation and administration, general laboratory systems, pre-analytic systems, analytic systems, and post analytic systems and to establish and maintain the quality assessment program for the histopathology and cytology subspecialty laboratory testing. Findings included: 1- No adequate testing space and no utilities (no eyewash station) in the laboratory. Refer to D3001. 2- Laboratory floor had several loose wooden rectangular tiles- physical safety hazards. Refer to D3011. 3- No yearly competency review for clinical consultant. Refer to D5209. 4- Failure to follow the procedure manual for; (a) proficiency testing protocol, eye wash station, microscope maintenance, and computer key boards. (b) Refrigerator temperature; external thermometer calibration. Refer to D5407. 5- Failure to monitor humidity and room temperature, no monitoring device. Refer to D5413. 6- Expired reagents. Refer to D5417. 7- No microscope maintenance and no records. Refer to D5429. On 2/2/18 at 5:40PM testing person confirmed; A)

	findings 1 to 7. (B) that there was no corrective action. (C) that there were no quality assessment records for the findings 1 to 7 to determine whether corrective actions taken to resolve problems were effective. (D) that there was no documentation to indicate that policies and procedures were revised to prevent recurrence of problems.