Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2075815	02/26/2024
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
D0000	A recertification survey was conducted on February 26, 2024. Dr Prosper Abitbol PA clinical laboratory was not in compliance with 42 CFR 493, requirements for clinical laboratories.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on review of temperature logs, and interview, the laboratory failed to maintain documentation of the temperature logs for the room temperature and humidity of the laboratory for seven (August 2023 - February 2024) of 24 months (March 2022 to February 2024) reviewed. Findings: Review of the Laboratory Temperature Logs for the room temperature and humidity revealed the month of August 2023 - February 2024 were missing. On 02/26/2024 at 3:30 PM, Testing Personnel A stated she did not know where the temperature logs were located.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.

	This CONDITION is not met as evidenced by: Based on observation, record review, and interview, the laboratory failed to follow manufacturer's instructions for storing the Schiff's Reagent from 05/18/23 to 2/26/24. (See D5411), failed to document the making of the 70 % and 95 % alcohol solutions used on the Sakura Tissue Tek VIP (Vacuum Infiltration Processor) from 02/08/2022 to 02/26/2024, failed to record the temperature of the refrigerator where reagents were stored from 03/2022 to 02/23/2024 (See D5413), failed to document the making of the 70 % and 95 % alcohol solutions used on the Sakura Tissue Tek VIP (Vacuum Infiltration Processor) from 02/08/2022 to 02/26/2024 and failed to document the making of the 95 % alcohol solution used on the Leica Autostainer XL from 02/08 /2022 to 02/26/2024 (See D5415).
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on observation, review of temperature logs, and interview, the laboratory failed to follow manufacturer's instructions for storing the Schiff's Reagent from 05/18/23 to 2/26/24. Findings: During a tour of the laboratory on 02/26/2024 at 1:30 PM, two bottles of Schiff's Reagent (lot #2308608 expiration date 03/30/2024 and lot #2326129 expiration date 09/21/2024) were found in the refrigerator. The label on the bottle for lot #2308608 noted "Store in refrigerator (2 - 8 degrees. C" (Celsius) and was dated 05/18/2023. The label on the bottle for lot #2308608 noted "Store in refrigerator (15 degrees - 30 degrees C)" and listed an open date of 11/01/2023. On 02 /26/24 at 1:39 PM, the temperature reading on the thermometer was 11.4 degrees C. Review of the Refrigerator Temperature Chart showed the laboratory placed a check mark indicating the temperature was in the range from 1 - 11 degrees C. On 02/26 /2024 at 1:31 PM, Testing Personnel A acknowledged the Schiff's Reagent may not have always been stored according to the temperature ranges on the bottles.
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 review of temperature logs, and interview, the laboratory failed to record the temperature of the refrigerator where reagents were stored from 03/01/2022 to 02/23 /2024. Findings: Review of the Refrigerator Temperature Chart showed the laboratory

	placed a check mark indicating the temperature was in the range between 1 - 11 degrees Celsius. On 02/26/2024 at 1:31 PM, Testing Personnel A acknowledged they put a check mark when the temperature was in range, and did not know they needed to record the actual temperatures.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on observation, review of quality control documents, review of the laboratory's 2022 Plan of Correction, and interview, the laboratory failed to document the making of the 70 % and 95 % alcohol solutions used on the Sakura Tissue Tek VIP (Vacuum Infiltration Processor) from 02/08/2022 to 02/26/2024. The laboratory failed to document the making of the 95 % alcohol solution used on the Leica Autostainer XL from 02/08/2022 to 02/26/2024. This was a repeat deficiency from the recertification survey on 01/24/2022. Findings: Examination of the Sakura Tissue Tek VIP on 02/26 /2024 at 1:35 PM, showed the processor used the following reagents: Alcohol 100 %, Alcohol 95 %, Alcohol 70 %, Formalin 10%, Safeclear and Paraffin. Examination of the Leica Autostainer XL on 02/26/2024 at 1:35 PM, showed the stainer used the following reagents: Safeclear, Alcohol 100 % and 95 %, Hematoxylin, Eosin, Bluing, High Def and Acetic Acid 3 %. Examination of the flammable cabinet 02/26/2024 at 1:40 PM revealed it only contained bottles of 100 % Alcohol. Review of the laboratory's quality control documents revealed the laboratory did not have documentation of the preparation of the 95 % Alcohol and 70 % Alcohol. Review of the laboratory's Plan of Correction for the recertification survey on 01/24/2022, revealed the response to how the deficient practice will be corrected was "The implementation of a Reagent Preparation Log for the Sakura Tissue Tek VIP and Leica AutoStainer XL. This log was created February 3, 2022, and will be implemented on February 8, 2022." On 02/26/2024 at 4:16 PM, Testing Personnel A stated the did not fill out the preparation log.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on record review, and interview, the Laboratory Director failed to ensure quality controls were maintained from 02/08/2022 to 02/26/2024. (See D6093)
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)

	The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on record review, and interview, the Laboratory Director failed to ensure quality controls were documented and failed to identify problems from 02/08/2022 to 02/26/2024. Findings: The laboratory failed to follow manufacturer's instructions by storing the Schiff's Reagent from 05/18/23 to 2/26/24. (See D5411) The laboratory failed to record the temperature of the refrigerator where reagents were stored from 03 /2022 to 02/23/2024. (See D5413) The laboratory failed to document the making of the 70 % and 95 % alcohol solutions used on the Sakura Tissue Tek VIP (Vacuum Infiltration Processor) from 02/08/2022 to 02/26/2024. The laboratory failed to document the making of the 95 % alcohol solution used on the Leica Autostainer XL from 02/08/2022 to 02/26/2024. (See D5415).
D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: Based on review of college transcripts and competency evaluations, and interview, the laboratory failed to ensure one (B) of two (A, B) testing personnel had at least 24 semester credit hours in science courses. (See D6171)
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2) (ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could

have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations.

This STANDARD is not met as evidenced by:
Based on review of college transcripts, competency evaluations, and interview, the laboratory failed to ensure one (B) of two (A, B) testing personnel had at least 24 semester credit hours in science courses. Findings: Review of the CMS 209 Laboratory Personnel Report, signed by the Laboratory Director on 02/26/2024, showed there were two employees listed as high complexity testing personnel. Review of Competency Assessment forms for Testing Personnel B showed Date of Assessment for the task of grossing was performed on 02/23/2022 and 01/25/2023 Review of the Report of Evaluation of Educational Credentials showed Testing Personnel B's foreign degree was the equivalent to the United States (US) degree of Bachelor of Science in Business Administration. Review of the transcripts in the report showed only three semester credits in biology. Review of the transcripts from a college in the US showed only eight semester credits in biology. On 02/26/2024 at 5: 17 PM, Testing Personnel B stated she did not know how many science classes she had..