Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2328667	02/20/2026
Name of Provider or Supplier	**Street Address, City, State**	
Parkland Medspa & Wellness Center	7383 N State Road 7, Parkland, 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 announced CLIA initial survey was conducted at PARKLAND MEDSPA & WELLNESS CENTER from 02/03/2026 to 02/20/2026. The laboratory was not in compliance with 42 CFR Part 493, Requirement for Laboratories. The following Conditions were cited: D2000 493.801 -Condition- Enrollment and Testing of Samples. D6000 493.1403 -Condition- Moderate Complexity Laboratory Director. D6033 493.1409 - Condition-Technical Consultant-Moderate Complexity.
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on lack of records and staff interview, the laboratory failed to enroll in a Proficiency Testing (PT) program approved by the Department of Health and Human Services (HHS) and Centers for Medicare and Medicaid Services (CMS) for Testosterone and Prostatic Specific Antigen (PSA) since 09/10/2025. Findings included: 1-Review of test menu listed on Form CMS-116 signed by the Owner on 02 /03/2026, the laboratory performed the following tests: Testosterone and Prostatic Specific Antigen (PSA) and with an annual estimated volume of 120 tests. 2-The laboratory had no PT records for 2025 and no proof of enrollment for 2026 3-During an interview on 02/03/2026 at 12:30 PM, the Owner confirmed that the laboratory did not have any records and was not enrolled for PT for 2026.

D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) (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 record review and staff interview, the Laboratory Director (LD) failed to approve, sign, and date the procedure manual before Patient testing on 09/10/2025. Findings included: 1-Review of Nano Entek Moderate complexity CLIA Compliance Manual, revealed that on page 4 had a log for acceptances of "SOP POLICIES AND ROSTER OF TESTING PERSONNEL", this log was blank no signatures to confirm review and approval. No signatures of the LD founded in any of the other pages of the manual. 2-The laboratory tested 13 patients since 09/10/2025. 2- During an interview on 02/03/2026 at 12:30 PM, the Owner confirmed that the LD failed to sign the procedure manual.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(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 lack of records and staff interview, the laboratory failed to monitor room humidity and temperature to ensure optimal operation for the Nano Entek since 09/10 /2025 to present. II-Based on lack of records and staff interview, the laboratory failed to document the refrigerator temperature for the storage of the Testosterones and Prostatic Specific Antigen (PSA) reagents since 09/10/2025. III-Based on lack of records and staff interview the laboratory failed to monitor the freezer temperature for the storage of the NOD liquid assayed immunoassay controls level 1 and 2 since 09/10 /2025. The findings included: I 1-Review of Nano Entek Analyzer manual revealed a requirement for optimal operation a range of room temperature of 15 to 30 C and Humidity between 10 to 80 %. 2-The laboratory had no records to document the room temperature and room humidity. 3-During an interview on 02/03/2025 at 11:30 AM, Testing Personnel #1 confirmed that there was no documentation of the room temperature and humidity for the period of reference. II 4- Review of Frend Testosterone and PSA Instructions for use (IFU), revealed that there was a requirement to store the cartridges of the kit at 2-8 C, the laboratory had no documentation of refrigerator temperature monitoring. 5-During an interview on 02/03 /2025 at 11:35 AM, Testing Personnel #1 confirmed that there was no documentation of the refrigerator temperature for the period of reference. III 6- Review of NOVA-ONE DIAGNOSTICS, NOD Frend Immunoassay Control Kit Instructions for use (IFU), revealed that there was a requirement of storage of the controls at temperature below -11 C. The laboratory had no documentation of freezer temperature

	monitoring. 7- During an interview on 02/03/2026 at 12:30 PM, the Owner confirmed that the laboratory did not monitor the temperature of the freezer.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) (c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on observation, review of package insert, and staff interview, the laboratory failed to properly label Nova-One Diagnostics Quality Control (QC) vials on 02/03 /2026 with open date and new expiration date. Findings included: 1-During the laboratory tour on 02/03/2026 at 10:45 AM, the surveyor observed that the laboratory was using NOVA-ONE Diagnostics QC in the FREND IMMUNOASSAY analyzer. The laboratory had Control level 1 and 2 with Lot number 6361A 25001 for Testosterone and PSA (Prostate Specific Antigen), the vials had no open date and new expiration date. 2-Review of the Nova-One Diagnostics Control user instructions revealed that used controls had an expiration date of 30 days after first use, the laboratory could not provide documentation when the laboratory opened the vials in use. 3--During an interview on 02/03/2026 at 11:40 AM the Testing Personnel #1 confirmed that the QC vials were not labeled with the new expiration date.
D5427	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(c) (c) Documentation. The laboratory must document all activities specified in this section. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to have documentation that the Laboratory Director (LD) reviewed and approved of the Nano Entek Frend system before patient testing on 09/10/2025. The findings included: 1-Review of the performance and verification study for the Frend with Serial Number 2410001-087, revealed that the study failed to have the acceptance signature of the LD. The laboratory tested 13 patients for Testosterone and Prostatic Specific Antigen (PSA) from 09/10/2025 to present. 2-During an interview on 02/03/2026 at 11:50 AM, the Owner confirmed that the laboratory failed to have the documentation that the LD reviewed and signed the verification of performance of the Frend analyzer.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

	This CONDITION is not met as evidenced by: Based on record review and staff interview, the laboratory director (LD) failed to effectively oversee the laboratory since September 2025 to present. Findings included: -Failed to ensure the laboratory had a qualified Technical Consultant. See D6004. -Failed to establish a policy to be onsite once every six months and document the onsite visits. See D6005. -Failed to ensure the laboratory enrolled in Proficiency Testing during 2025. See D6015. -Failed to assess personnel competencies. See D6029.
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, 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 interview, the Laboratory Director (LD) failed to effectively oversee the laboratory. Findings included: 1-The LD failed to ensure the laboratory had all Proficiency Testing records. See D6015. 2-The LD failed to ensure the laboratory had a qualified Technical Consultant. See D6035.
D6005	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(c) (c) The laboratory director must: (c)(1) Be onsite at least once every 6 months, with at least 4 months between the minimum two on-site visits. Laboratory directors may elect to be on-site more frequently and must continue to be accessible to the laboratory to provide telephone or electronic consultation as needed; and (c)(2) Provide documentation of these visits, including evidence of performing activities that are part of the laboratory director responsibilities. This STANDARD is not met as evidenced by: Based on record review and staff interview, the Laboratory Director (LD) failed to establish a policy to be onsite once every six months and document the onsite visits. Findings included: 1-Based on lack of documentation signed by the LD and review of the procedure manual (not signed by the LD), revealed that the Laboratory had no documentation of the visits of the LD 2- During an Interview on 02/03/2026 at 12.46 PM, the Owner confirmed that there was no policy to monitor the LD visits to the laboratory and that the laboratory failed to have documentation of the LD visits on site.
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)

	(e)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed and that-- This STANDARD is not met as evidenced by: Based on lack of records and staff interview, the Laboratory Director (LD) failed to ensure that the laboratory enrolled and participated in Proficiency Testing (PT) for the Testosterone and Prostatic Specific Antigen (PSA) testing since September 2025. Findings included: 1-Review of Form CMS-116, signed by the Laboratory Director on 02/03/2026, revealed that the laboratory was doing the following tests: Testosterone and Prostatic Specific Antigen (PSA) and with an annual estimated volume of 120 tests. 2-The laboratory had no proficiency testing records for 2025, and the laboratory was not enrolled for PT for 2026. 3- During an Interview on 02/03/2026 at 11:40 AM, the Owner confirmed that the LD failed to ensure the laboratory was enrolled in PT for Testosterone and PSA in 2025 and 2026.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) (e)(11) Ensure that prior to testing patients specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results; This STANDARD is not met as evidenced by: Based on lack of records and staff interview, the Laboratory Director (LD) failed to ensure the Testing Personnel (TP) had competency evaluation before Patient testing in September 2025. Findings included: 1-Review of TP personnel records revealed that there was no competency evaluation done by the Technical Consultant/LD. 3- During an Interview on 02/03/2026 at 11:45 AM, the Owner confirmed that the LD failed to ensure TP had competency evaluation before Patient testing since September 2025.
D6033	TECHNICAL CONSULTANT-MODERATE COMPLEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based in record review and staff interview, the laboratory failed to have a qualified Technical Consultant for overseeing testing of Testosterone and Prostate Antigen Specific (PSA). See D6035.
D6035	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 (a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the

	laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology; or (b)(2)(i) 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; AND (b)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i)(A) Hold an earned doctoral or master's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(3)(i)(B) Meet either requirements in 493.1405(b)(3)(i)(B) or (b)(4)(i)(B) or (C); AND (b)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i)(A) Have earned a bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(4)(i)(B) Meet 493.1405(b)(5)(i)(B); and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(5)(i) Have earned an associate degree in medical laboratory technology, medical laboratory science, or clinical laboratory science; and (b)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. (b)(6) For blood gas analysis, the individual must- (b)(6)(i) Be qualified under paragraph (b)(1), (2), (3) or (4) of this section; or (b)(6)(ii)(A) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; and (b)(6)(ii)(B) Have at least 2 years of laboratory training or experience, or both, in blood gas analysis; or (b)(7) Notwithstanding any other provision of this section, an individual is considered qualified as a technical consultant under this section if they were qualified and serving as a technical consultant for moderate complexity testing in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to have a qualified Technical Consultant (TC) since September 2025. Findings included: 1-Review of FORM CMS-209 signed by the Laboratory Director (LD) on 02/03/2026, revealed that the LD was also the Clinical Consultant (CC) and TC. Review of the LD resume revealed that the LD failed to have at least one year of experience overseeing moderate complexity testing. 2- During an interview on 02/03/2026 at 12:30 PM, with the Owner, he explained that the LD resume listed experience as Urgent Care Doctor, notification via email on 02/17/2026, from the LD confirmed that the laboratory he was involved before was a Waived certificate that does not meet the criteria for TC.