Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2226899	04/02/2025
Name of Provider or Supplier	**Street Address, City, State**	
Dr Edwin Maldonado, Md Pl	160 Congress Park Drive Suit 101, Delray Beach, 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 recertification survey was conducted at Dr Edwin Maldonado MD PA on April 2, 2025. The laboratory was not in compliance with 42 CFR Part 493, Requirement for Laboratories. The following Conditions were cited: D3000 - Facilities 493.1101 D5400- Analytic Systems 493.1250
D3000	FACILITY ADMINISTRATION CFR(s): 493.1100 Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). This CONDITION is not met as evidenced by: Based on review of the Clinical Laboratory Improvements Amendments (CLIA)) Applications, observation, and interview, the laboratory failed to have separate supplies for Toxicology testing from 05/07/2024 to 04/02/2025. This is a repeat deficiency from the Initial survey on 04/12/2023. (See D3007)
D3007	FACILITIES CFR(s): 493.1101(b) (b) The laboratory must have appropriate and sufficient equipment, instruments, reagents, materials, and supplies for the type and volume of testing it performs. This STANDARD is not met as evidenced by: Based on review of the Clinical Laboratory Improvements Amendments (CLIA)) Applications, observation, and interview, the laboratory failed to have separate supplies for Toxicology testing from 05/07/2024 to 04/02/2025. This is a repeat

	deficiency from the Initial survey on 04/12/2023. Findings: Record review of the CLIA Applications for this laboratory (Lab A) and another Certificate of Compliance laboratory (Lab B) revealed the two laboratories were located at the same physical address. During a tour of the laboratory on 04/02/2023 at 9:25 AM, there was a single Abbott ImmTox 270 instrument located in the laboratory. This Toxicology instrument was being used by Lab A and Lab B. During a tour of the laboratory on 04/02/2025 at 9:25 AM, it was noted the laboratory had one bottle of Acid Washing Solution (lot #240729) and one bottle of Alkaline Washing Solution (lot #240730). No other bottles of the wash solutions were found. Review of the CMS 116 signed by the Laboratory Director on 03/25/2025 revealed the Laboratory performed Toxicology screens for the following drugs: Amphetamine, Barbiturates, Benzodiazepines, Benzoylecgonine, Buprenorphine, EDDP (Methadone primary metabolite), Methamphetamine, Opiates, Oxycodone, and, Phencyclidine. The annual testing volume was documented as 15,000. On 04/02/2025 at 9:25 AM, the Technical Consultant stated they used the two bottles of wash solutions for each laboratory.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of the test menu, procedure manual and Proficiency Testing (PT) records, and interview, the laboratory failed to verify the accuracy (PT) of their Toxicology testing between 05/01/2024 and 12/31/2024. Findings: Review of the CMS 116 signed by the Laboratory Director on 03/25/2025 revealed the Laboratory performed Toxicology testing for the following drugs: Amphetamine, Barbiturates, Benzodiazepines, Benzoylecgonine, Buprenorphine, EDDP (Methadone primary metabolite), Methamphetamine, Opiates, Oxycodone, and Phencyclidine. Review of the procedure titled, Proficiency Testing (PT) read, "For those analytes (non-regulated analytes) which are not included in a formal proficiency testing program, the laboratory must provide a method to assess and verify the accuracy and reliability of their analytes." Review of the PT records showed there was no PT performed from 05 /01/2024 and 12/31/2024 for their moderate complexity Toxicology analytes. During an interview on 04/02/2025 at 1:38 AM, the Technical Consultant stated the laboratory switched to moderate level complexity on 05/01/2024. During an interview on 04/02/2025 at 10:38 AM, the Technical Consultant acknowledged there was no PT done between 05/01/2024 and 12/31/2024.
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 record review, and interview, the Laboratory failed to complete performance specifications for their urine stability study for drug screening test before patient testing. (See D5423)
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) (b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (b)(2)(i) Accuracy. (b)(2)(ii) Precision. (b)(2)(iii) Analytical sensitivity. (b)(2)(iv) Analytical specificity to include interfering substances. (b)(2)(v) Reportable range of test results for the test system. (b)(2)(vi) Reference intervals (normal values). (b)(2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on record review and interview, the Laboratory failed to complete performance specifications for their urine stability study for drug screening test before patient testing. Findings: Review of drug test menu revealed the following drugs were tested for: Amphetamine Barbiturate Benzodiazepine Cocaine Metabolite EDDP Specific Methamphetamine Opiates Oxycodone Phencyclidine Review of Buprenorphine Urine HEIA assay package insert read, "Urine specimens may be stored at 22-30 degrees Celsius (C) for up to 3 days prior to analysis." Review of specimen stability study revealed temperatures were not recorded and negative urine specimens were not used for stability study for 7 days. Review of Corrective Action Form read, "For self-inspection, all reagent package inserts were reviewed. Upon review, it was found that several did not meet the 2 week stability at room temperature: PCP, EDDP, BE, BUP, and BNZ. Abbot labs (reagent manufacturer) were contacted and the laboratory was informed that only stability studies at room temperature had been conducted." The laboratory kept all samples in a refrigerator prior to testing. A stability study was retroactively performed and was currently ongoing. The last day of the study would be 04/03/2025. The specimen stability study was not complete at the time of the survey. Review of Patient Report revealed Patient #1 was collected on 05/06/2024 and reported on 05/10/2024 for drug screening testing. On 04/02/2025 at 11:54 AM, the Testing Personnel confirmed temperatures were not recorded and negative urine specimens were not used for the stability study.
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on the review of the procedure manual, personnel record and interview, the

	Technical Supervisor failed to document the high complexity Toxicology training of 1 Testing Personnel of 1 Testing Personnel (A) from May 2023 to November 24, 2023. Findings: Review of the procedure manual noted, "New employees will not be cleared to perform tasks independently until their training checklist for this task is completed." Review of the personnel records for Testing Personnel A showed there was no documentation that indicated Testing Personnel A had received high complexity Toxicology training. During an interview on 04/02/2025 at 9:38 PM, the Technical Consultant who was also Testing Personnel A stated she started in May 2023 as a high complexity testing personnel and performed high complexity testing from May 2023 to November 24, 2023. The Technical Consultant also stated, she did not have documentation of her high complexity Toxicology training.