Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D1093166	03/20/2024
Name of Provider or Supplier	**Street Address, City, State**	
Joseph E Mouhanna Md Pa	7575 Sw 62 Ave Suite B, Miami, 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 conducted on 03/20/2024 found the JOSEPH E MOUHANNA MD PA clinical laboratory not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following Conditions were cited: -D5400 Analytic Systems 493.1250. -D6000 Moderate Complexity Laboratory Director 493.1403.
D3037	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years. This STANDARD is not met as evidenced by: Based on review of American Proficiency Institute (API) records and interview with Testing Person (TP), the laboratory failed to retain the instrument printout for one (2nd event of 2022) out of four (1st and 2nd events in 2022 and 2023) events reviewed for Toxicology. Findings included: Review of API Proficiency Testing records for 2022 and 2023 revealed that the laboratory failed to have instrument printout for second event of 2022 for Toxicology. During an interview on 03/20/2024 at 3:35 PM, the TP confirmed that the laboratory failed to retain the instrument printout for the event of reference.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on review of API (American Proficiency Institute) proficiency testing (PT) records and interview with Testing Personnel (TP), the laboratory failed to have

	corrective action for failed score for Urine Cocaine Metabolites and Urine Opiates for 1 (1st event 2022) out of 4 (1st and 2nd events in 2022 and 2023) events reviewed. Findings included: API PT records review revealed that the laboratory received a score of 67% for Urine Cocaine Metabolites and 33% for Urine Opiates in the first event of 2022. No corrective action documentation was found for this failure. During an interview on 03/20/2024 at 3:30 PM, TP confirmed that the laboratory had no documentation of the corrective action for the failed score in Toxicology.
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 staff interview, the laboratory failed to run positive and negative controls with patients every testing date (Refer to D5449) and failed to document the Quality Assessment (Refer to D5791).
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on lack of records and interview, the laboratory failed to run positive and negative external quality control (QC) for 49 out of 49 testing dates using the Immunalysis Opiates, Benzoylecgonine (Cocaine metabolite) and Oxycodone Urine Enzyme Immunoassay (HEIA) test kits from 06/01/2023 to 01/15/2024. Findings included: -Review of the test menu in the form CMS-116 (12//21) signed by the Laboratory Director on 03/07/2024, revealed that the laboratory performed the following tests from Immunoalysis: Opiates, Benzoylecgonine (Cocaine metabolite) and Oxycodone Urine Enzyme Immunoassay. -Review of ImmTox 270 "Drug Screen" policy signed by Laboratory Director (LD) on 05/30/2023 revealed that on section "Prepare Quality Control" it stated to "Verify QC passes before running patient samples". Review of "Quality Control Program" policy signed by the LD on 04 /23/2023 revealed that on section "Procedure" stated: "Qualitative tests require a negative and positive control (when applicable)" and on section "Documentation" stated that "QC log is filled out and reviewed each day samples are run." -The laboratory had no records that QC has being run since the ImmTox 270 instrument implementation on 05/30/2023. -Review of patient reports revealed the following testing days and patients tested per day as follows: 06/01/2023: 3 patients tested, 06/05 /2023: 17 patients tested, 06/07/2023: 8 patients tested, 06/08/2023:2 patients tested,

	06/09/2023: 6 patients tested, 06/13/2023: 14 patients tested, 06/16/2023: 12 patients tested, 06/20/2023: 14 patients tested, 06/21/2023: 4 patients tested, 06/22/2023: 5 patients tested, 06/27/2023: 14 patients tested, 07/05/2023: 22 patients tested, 07/11 /2023: 24 patients tested, 07/12/2023: 5 patients tested, 07/18/2023: 18 patients tested, 07/19/2023: 3 patients tested, 07/26/2023: 19 patients tested, 07/31/2023: 20 patients tested, 08/01/2023: 4 patients tested, 08/04/2023: 10 patients tested, 08/08/2023: 10 patients tested, 08/14/2023: 18 patients tested, 08/18/2023: 10 patients tested, 08/24 /2023: 24 patients tested, 08/25/2023: 1 patient tested, 09/06/2023: 36 patients tested, 09/08/2023: 15 patients tested, 09/15/2023: 14 patients tested, 09/19/2023: 11 patients tested, 09/25/2023: 16 patients tested, 10/06/2023: 50 patients tested, 10/13/2023: 22 patients tested, 10/20/2023: 13 patients tested, 10/23/2023: 9 patients tested, 10/30 /2023: 26 patients tested, 11/03/2023: 18 patients tested, 11/10/2023: 26 patients tested, 11/14/2023: 2 patients tested, 11/20/2023: 21 patients tested, 11/28/2023: 10 patients tested, 11/30/2023: 17 patients tested, 12/10/2023: 9 patients tested, 12/11 /2023: 24 patients tested, 12/20/2023: 25 patients tested, 01/09/2024: 55 patients tested, 01/12/2024: 11 patients tested, 01/15/2024: 6 patients tested, 01/22/2024: 12 patients tested, 01/24/2024: 1 patient tested. A total of 736 patients were tested without using external controls. During an interview on 03/20/2024 at 04:00 PM the laboratory consultant confirmed that the laboratory failed to run external controls before patient testing on the days that the 736 tests were performed.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on lack of records and interview, the laboratory failed to have documentation of the Quality Assessment (QA) activity that failed to correct and identify that the laboratory was not using external controls before patient testing since 06/01/2023 to present, and failed to ensure the laboratory took a corrective action for the Proficiency testing (PT) failure in the second event of 2022. This is a repeated deficiency of the recertification survey completed on 04/22/2022. Findings included: -Review of "Quality Assessment" policy signed by the Laboratory Director (LD) on 04/23/23 revealed that stated the following on Section: "How to perform a QA Review" "End of the month must be performed consistently within the following month. 1. End of the month document review, consists of the review of the following documents by the Laboratory Director/Technical Consultant/Lab Manager a) QC b) Calibration c) Environmental Logs d) Maintenance Logs e) Complaints/communications issues f) Proficiency Testing reports g) Competency exams h) Any corrective action logs such as when the LIS, instrument, QC or calibration issues extended beyond the scope of the technician and requires outside service to resolve the issue. 2. QA Review documentation" -The laboratory had no records of QA. -Review of laboratory records for 2022 and 2023 revealed the following: -No documentation of the corrective action required for the failure in proficiency testing. Refer to D5211. -No corrective action for not performing Quality Control before patient testing since 06/01/2023 to present. Refer to D5449. During an interview on 03/20/2024 at 2:00 PM, the laboratory consultant confirmed that there was no QA documentation and that the QA failed to correct the deficiency of not running controls every testing day since 06/01/2023. -

	Review of the Plan of Correction from the recertification survey completed 04/22 /2022 and signed by the laboratory director on 05/13/2022 revealed the following: " .... To correct this deficient practice quality assurance will be performed and documented monthly"; "A schedule was created, printed and placed in the laboratory and that the medical director will be monitoring this gets completed to ensure this deficiency does not repeat."
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 failed to effectively oversee the laboratory for 2 (2022-2024) out of 2 years reviewed. Findings include: -The laboratory director failed to ensure that the laboratory did a corrective action for a failure in proficiency testing in 2022. Refer to D6019. - The laboratory director failed to ensure that the laboratory performed quality control before patient testing since 06/01/2023 and failed to ensure the laboratory documented the quality assessment during 2022 and 2023. Refer to D6022.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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. (e) The laboratory director must-- (e)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on review of API (American Proficiency Institute) proficiency testing (PT) records and interview with Testing Personnel (TP), the laboratory failed to have corrective action for failed score for Urine Cocaine Metabolites and Urine Opiates for 1 (1st event 2022) out of 4 (1st and 2nd events in 2022 and 2023) events reviewed (Refer to D5221).
D6022	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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. (e) The laboratory director must-- (e)(5) Ensure that the quality control and quality assessment programs are established and maintained 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 (LD) failed to ensure the laboratory ran quality controls before patient testing from 06/01/2023 to present (Refer to D5449). The LD failed to ensure the laboratory documented the quality assessment (Refer D5791).