Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D1093166	04/22/2022
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	An initial certification survey conducted at JOSEPH E MOUHANNA MD PA on 04/18-22/2022 found the clinical laboratory was not in compliance with 42 CFR Part 493, Requirements for Laboratories.
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 record review and staff interview, the laboratory failed to keep the signed attestation for 1 out of 1 event reviewed for Toxicology. Findings include: Review of American Proficiency Institute (API) PT records for 2021, revealed that the laboratory failed to have the signed attestation for second Event 2021 for the specialty of Toxicology. During an interview on 04/22/2022 at 10:30 AM, the Office Manager confirmed that the laboratory failed to have signed attestation for the event of reference.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on records review and staff interview, the Laboratory Director (LD) failed to document the review and evaluation of Proficiency Testing (PT) for 1 (second event 2021) out of 1 event for the specialty of Toxicology. Findings include: Review of American Proficiency Institute (API) PT records showed the LD failed to sign the

	"Proficiency Performance Evaluation" form for the second event of 2021. During an interview on 04/18/2022 at 3:00 PM, the Office Manager confirmed that the LD failed to sign the "Proficiency Performance Evaluation" form for the PT second event of 2021.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on lack of records and staff interview, the laboratory failed to perform a calibration verification for the Biolis 24i Analyzer from Carolina Chemistries Corp at least every six months since June 2021 to present. Findings include: -Review of Biolis 24i Analyzer records, revealed that the laboratory failed to perform the calibration verification since June 2021 to present, in this period the laboratory tested 1272 patients. During an interview on 04/22/2022 at 11:00 AM, the office manager confirmed that the laboratory failed to perform instrument calibration verification at least every 6 months since June 2021 to present.
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 staff interview, the laboratory failed to follow the Quality Assurance (QA) policy from June 2021 to present. Findings include: -A Review of Quality Assessment policy revealed that the laboratory will review and document monthly the QA activity. -No records found of the QA activity since June

	2021 to present. During an interview on 04/22/2022 at 11:05 AM, the Office Manager confirmed that the laboratory failed to document the QA activity since June 2021 to present.