Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D2047943	06/03/2024
Name of Provider or Supplier	**Street Address, City, State**	
Ayman Tarabishy Md Pllc	42645 Garfield Road Ste 103, Clinton Township, MI	

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
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: . Based on observation, record review and interview with the Technical Consultant, the laboratory failed to ensure protection from chemical and biohazardous materials for 7 (October 2023 to May 2024) months since the laboratory changes locations. Findings include: 1. The surveyor observed the laboratory on 6/3/24 at 9:25 am and noticed a lack of eyewash station. 2. A review of the laboratory's "General HAZCOM Training Program" policy revealed a section stating, "Preliminary first aid for hazardous material exposure. Chemicals in the eyes. Don't rub the eyes. Hold the eyelids open and flush eyes with clean water. Continue for 15 to 20 minutes." 3. An interview on 6/3/24 at 9:25 am with the Technical Consultant confirmed the laboratory did not have and eyewash station in the laboratory after the laboratory had moved locations in October 2023.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.

	This STANDARD is not met as evidenced by: . Based on observation, record review, and interview with Testing Personnel #1, the laboratory failed to follow its specimen acceptability and rejection policies for one urine specimen cup observed. Findings include: 1. The surveyor observed urine cups on the counter of the laboratory on 6/3/34 at 9:24 am and noticed a specimen labeled with a patient's first and last name and the date of collection. 2. A review of the laboratory's "Specimen Collection" policy revealed a section stating, "The container must have a label that will ashere under refrigeration. The label must include the patient's identification and the date and time of specimens collection and the date and time of specimen collection and the labels must e place on the container, not the lid" and "Label the container with the patient's name, number, and time and date of collection; an intake volume may also be needed." 3. An interview on 6/3/24 at 9:33 am with Testing Personnel #1 revealed testing would be performed on the specimen labeled only with the first and last name and date of collection.
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 record review and interviews, the laboratory failed to monitor the specimen freezer temperatures when used to store specimens for 2 (Patients 2 and 3) of 12 patient test records reviewed. Findings include: 1. A review of the laboratory's test procedures revealed urine toxicology specimens for opiates, cocaine, and benzodiazepines had a section titled "Specimen Collection and Handling" stating, "Use fresh urine specimens for the test. If a sample cannot be analyzed immediately, it may be refrigerated at 2-8 degrees C for up to seven days. For longer storage, keep sample frozen at -20 degrees C and then thaw before use." 2. A review of 12 patient test records revealed the following patients were tested beyond seven days after collection: a. Patient 2 had urine collected on 3/5/24 and testing reported on 3/13/24. b. Patient 3 had urine collected on 2/13/24 and had testing reported on 2/21/24. 3. An interview on 6/3/24 at 10:45 am with Testing Personnel #1 revealed specimens that cannot be tested within seven days are frozen in the laboratory's freezer. 4. A review of the laboratory's temperature monitoring logs revealed a lack of documentation of temperature monitoring of the specimen freezer from May 2022 to May 2024. 5. The surveyor requested the laboratory's specimen freezer temperature monitoring on 6/3 /24 at 10:45 am and it was not made available.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the

	manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: . Based on record review and interview with the Technical Consultant, the laboratory failed to verify performance specifications for its Easy RA urine qualitative toxicology test system for 7 (October 2023 to May 2024) months since the laboratory location changed. Findings include: 1. An interview with the Technical Consultant on 6/3/24 at 9:25 am revealed the Easy RA urine qualitative toxicology analyzer was moved across the building to its current location in October 2023. 2. The surveyor requested documentation of the verification of performance specifications after the instrument was moved, but prior to patient testing on 6/3/24 at 9:25 am and it was not made available. 3. An interview with the Technical Consultant 6/3/24 at 9:25 am confirmed the laboratory did not verify performance specifications of the Easy RA urine qualitative toxicology analyzer after the instrument was moved and prior to patient testing.