Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2301329	11/21/2024
Name of Provider or Supplier	**Street Address, City, State**	
Amico Dx Llc	900 S Loop W Ste 170, Houston, TX	

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	The laboratory was surveyed and found to be in compliance with the Conditions of the CLIA regulations found at 42 CFR 493.1 through 493.1780, and recertification is recommended. Standard level deficiencies were cited.
D5317	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(d) If the laboratory accepts a referral specimen, written instructions must be available to the laboratory's clients and must include, as appropriate, the information specified in paragraphs (a)(1) through (a)(7) of this section. This STANDARD is not met as evidenced by: Based on surveyor observation, a review of the laboratory's records, and staff interview, the laboratory failed to provide written instructions to its clients for the patient preparation, collection, labeling, storage, transportation, processing, and acceptability/rejection criteria of specimens for one of one test performed by the laboratory from October to November 2024. Findings include: 1. Surveyor observation of the laboratory on 11/21/24 at 9:30 a.m. revealed the laboratory received patient's urine specimens from outside clients for toxicology testing. 2. A review of the laboratory's records revealed the laboratory failed to have documentation of providing written instructions to its clients for the patient preparation, collection, labeling, storage, transportation, processing, and acceptability /rejection criteria of specimens. 3. In an interview on 11/21/24 at 11:00 a.m. in the conference room, after review of the records, the laboratory director confirmed the above findings.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(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: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies, the laboratory's test records, and staff interview, the laboratory failed to have documentation of performing one of one stability study on urine samples used for toxicology testing on the Thermo Fisher Quantis Plus LC/MS System prior to patient testing. Findings include: 1. A review of the laboratory policy titled 'General Accession for Drugs of Abuse Screening and Confirmation Testing' revealed the following: "Sample is rejected if the following stability limit storage conditions are exceeded: - 7 days at room temperature - 7 days refrigerated at 2-8C - 30 days when stored frozen at -10C to -25C" 2. A review of the laboratory's test records revealed the laboratory started patient urine toxicology testing using the Thermo Fisher Quantis Plus LC/MS System in October 2024. 3. Further review of the laboratory's records revealed the laboratory failed to have documentation of performing a stability study that confirmed the stability limits listed in the General Accession for Drugs of Abuse Screening and Confirmation Testing policy. 4. In an interview on 11/21/24 at 10:30 a.m. in the conference room, after review of the records, the laboratory director confirmed the above findings. Key: LC /MS = Liquid Chromatography/Mass Spectrometry