Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2301329	06/29/2026
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 found to be in compliance with the Conditions of the CLIA regulations found at 42 CFR 493.1 through 493.1780, CLIA requirements for laboratories as a result of a routine recertification survey completed on 06/29/2026 and recertification is recommended. Standard level deficiencies were cited.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on the review of the laboratory's policy, CMS 209 Laboratory Personnel Report, the laboratory's records, personnel competency records, and confirmed in an interview, the laboratory failed to have documentation of competency assessment for 1 of 1 technical supervisor. The findings were: 1. Review of the laboratory's policy titled 7.0 Competency Assessment (QM-001 Rev.01) revealed "Competency assessment shall be performed in accordance with laboratory policy and applicable regulatory requirements." 2. Review of the laboratory's CMS 209 Laboratory Personnel Report, signed by the laboratory director on 06/15/2026, revealed the laboratory identified 1 technical supervisor. 3. Review of the laboratory's personnel competency records revealed the laboratory failed to have documentation of competency assessment for 1 of 1 technical supervisor. Technical supervisor: Hired date: February 19, 2024 4. In an interview on 06/29/2026 at 11:49 am in a conference room, technical supervisor confirmed the above findings. Key: CMS=Center of Medicare and Medicaid Services
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a)

	(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (a)(1) Patient preparation. (a)(2) Specimen collection. (a)(3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (a)(4) Specimen storage and preservation. (a)(5) Conditions for specimen transportation. (a)(6) Specimen processing. (a)(7) Specimen acceptability and rejection. (a)(8) Specimen referral. This STANDARD is not met as evidenced by: Based on the review of the laboratory's policy, the laboratory's temperature logs, patient logs, and confirmed in an interview, the laboratory failed to have a mechanism in place to ensure client specimen integrity temperature during transportation and upon arrival to the laboratory for 344 of 344 patient samples. The findings were: 1. Review of the laboratory's policy titled "SOP Sample Collection-Wound Infection Pathogens Test" (Document#: ADX_WOU_SC_v01) under Transport Conditions revealed "Most PCR samples can be transported at room temperature within 24 hrs or refrigerated if more than 24 hrs." 5. Review of the laboratory's policy titled "SOP Sample Collection-Nail Fungal Pathogens Test" (Document#: ADX_NF_SC_v01) under Packaging & Transport revealed "Place it in a dry container: ... Avoid moisture: ... Storage: Keep the dry specimen at room temperature and transport it to the lab as soon as possible." 3.In an interview on 06/29/2026 at 1:00 pm in a conference room, the technical supervisor stated the facility defined room temperature was 25 C and refrigerated temperature was 4C. The technical supervisor also stated the clients sent samples through FeEx overnight without any ice packs. 4. Review of the laboratory's temperature logs revealed the laboratory failed to have a mechanism in place to ensure client specimen integrity temperature during transportation and upon arrival to the laboratory for 344 of 344 patient samples. Refer to the attachment "Patient Logs" for list. 5. In an interview on 06/29/2026 at 1:45 pm in a conference room, the technical supervisor confirmed the above findings. Key: PCR=Polymerase Chain Reaction C=Celcius degree
D5453	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(iv)(g) (d)(3)(iv) Each test system that has an extraction phase, include two control materials, including one that is capable of detecting errors in the extraction process; and This STANDARD is not met as evidenced by: Based on surveyor's direct observation, the review of the laboratory's extraction plate map template, quality control policies, patient testing extraction plate map from May to June 28, 2026, and confirmed in an interview, the laboratory failed to utilize two control materials for patient testing on the Kingfisher system, during the extraction phase, for 42 of 59 days reviewed. The findings were: 1. During a tour of the facility on 06/29/2026 at 11:40 am, the surveyor observed one KingFisher Flex Extraction System available for patient sample extraction. Thermo KingFisher Flex 96 SN: 711-83070 2. Review of the laboratory's patient testing logs revealed the laboratory started performing molecular diagnostic testing on 05/04/26 for wound panel testing. The laboratory started Nail Fungal molecular diagnostic panel testing on 05/26/26. 3. Review of the laboratory's extraction plate map template during patient testing and in an interview on 06/29/2026 at 12:10 pm in a conference room, technical supervisor confirmed the facility utilized only 1 negative control (NEC) according to review of

	the laboratory's extraction plate map template during patient testing. 4. Review of the laboratory's policies titled "Wound Infection Testing Quality Control (QC) Policy and Procedure" and "Nail Fungal Pathogen Testing Quality Control (QC) Policy and Procedure" under 2. Analytical Quality Control revealed "Controls In Extraction: Include a Reagent Blank (no-template control) during DNA extraction to verify that reagents are free of fungal/bacterial DNA. Negative extraction control (NEC)-Blank Amies medium is included in the extraction step. RNAse P is used as Extraction control. RNAse P should be positive in all samples except the NEC and Negative control NC." Wound molecular diagnostic panel testing 05/04/2026 05/06/2026 05/11 /2026 05/12/2026 05/13/2026 05/14/2026 05/15/2026 05/16/2026 05/19/2026 05/20 /2026 05/21/2026 05/22/2026 05/26/2026 05/28/2026 05/29/2026 06/02/2026 06/03 /2026 06/05/2026 06/06/2026 06/08/2026 06/09/2026 06/10/2026 06/11/2026 06/12 /2026 06/13/2026 06/17/2026 06/18/2026 06/20/2026 06/25/2026 06/27/2026 Nail Fugal molecular diagnostic panel testing 05/26/2026 05/28/2026 05/29/2026 06/02 /2026 06/03/2026 06/06/2026 06/09/2026 06/11/2026 06/13/2026 06/16/2026 06/20 /2026 06/24/2026 06/26/2026 4. In an interview on 06/29/2026 at 12:30 pm in a conference room, technical supervisor confirmed the above findings.
D5807	TEST REPORT CFR(s): 493.1291(d) (d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on the review of the laboratory's validation records, test patient final reports, and confirmed in an interview, the laboratory failed to ensure normal reference intervals were available to health care providers for 2 of 2 molecular diagnostic testing panels performed at the facility. The findings were: 1. Review of the laboratory's validation records revealed the laboratory validated Wound Infection Pathogen Panel and Nail/Fungal Infection Pathogens Panel. 2. Review of the laboratory's test patient final reports revealed the laboratory failed to ensure normal reference intervals were available to health care providers for 2 of 2 molecular diagnostic testing panels performed at the facility. Wound Infection Pathogen Panel Nail/Fungal Infection Pathogens Panel 3. In an interview on 06/29/2026 at 3:44 pm in a conference room, chief operating officer confirmed the above findings.
D6082	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1) (e) The laboratory director must-- (e)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing; This STANDARD is not met as evidenced by: Based on the review of the laboratory's test patient final reports, validation records, and confirmed in an interview, the laboratory director failed to define Ct values in analytic systems to determine results for 2 of 2 molecular diagnostic test panels performed by the laboratory started in May 2026. The findings were: 1. Review of the

	test patient final reports for wound molecular diagnostic panel testing and nail/fungal molecular diagnostic panel testing revealed under Tested Pathogen/Genes reported either Detected or Not Detected. 2. In an interview on 06/29/2026 at 2:00 pm in a conference room, the technical supervisor confirmed the Detected or Not Detected result was determined on the Ct Value. 3. Review of the laboratory's validation records signed of by the laboratory director on 05/01/2026, titled "Validation of BioPathogenic Wound V2 qPLEX kit" (Document#: ADX_Val_Wound_BPxV2_1) and "Validation of Nail Fungal BPX qPLEX Version 2" (Document#: ADX_Val_NF_BPXV2_1) revealed the laboratory director failed to define Ct values in analytic systems to determine detected or not detected result for 2 of 2 molecular diagnostic test panels performed by the laboratory started in May 2026. 4. In an interview on 06/29/2026 at 2:21 pm in a conference room, the technical supervisor confirmed the above findings. Key: Ct value: Cycle Threshold