Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 45D1039060	**(X3) Date Survey Completed** 10/14/2022
Name of Provider or Supplier University Of Texas Medical Branch Department	**Street Address, City, State** 301 University Blvd, Uhc Building, Galveston, 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	An entrance conference was held with the laboratory representative. The survey process was discussed and survey forms were provided. An opportunity for questions and comments was given. Noted deficiencies and plans of correction were discussed with the laboratory representatives at the exit conference. The laboratory representatives were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in COMPLIANCE with applicable Conditions of Participation in the CLIA program, and recertification is recommended. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
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 direct observation, review of operator's guides, laboratory environmental logs, and confirmed in interview, the laboratory failed to have a system in place to accurately monitor and document relative humidity in the sample processing area of

	the laboratory for 17 of 17 months (April 2021-September 2022). Findings Included: 1. During a tour of the laboratory, the surveyor observed 2 Thermo Scientific HM525 NX Cryostats and 1 Linistat Slide Stainer. 2. Review of the Thermo Scientific HM525 NX Cryostat Operator's Guide (Version 2.131) revealed the following: "Environmental Specifications Relative Humidity (RH): Max 60% RH up to 35 C" Review of Linistat Slide Stainer Operator's Guide (Version 100342.1) revealed the following: "Environmental Specifications Relative Humidity (RH): Max 80% RH up to 31 C. Decreasing linearly to 50% RH at 40 C" 3. Review of laboratory environmental logs revealed the laboratory failed to monitor and document relative humidity levels in the sample processing area for 17 of 17 months (April 2021-September 2022). 4. During an interview, in the dermatology office, on 10/14/2022 at 11:20 a.m. with Testing Person 2 (TP-2), listed on the Center for Medicare and Medicaid Services 209 form, TP-2 stated the laboratory did not monitor or document relative humidity in the sample processing area. This confirmed the above findings.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, laboratory policy, quality control (QC) records, and confirmed in staff interview, the laboratory failed to define the intended reactivity for Hematoxylin and Eosin (H&E) staining to ensure predictable staining characteristics of quality control slides on each day of patient testing for 17 of 17 months (April 2021-September 2022). Findings Included: 1. During a tour of the facility, TP-2 was asked to provide the manufacturer's instructions for the H&E stain used in sample processing. TP-2 was unable to provide the manufacturer's instructions listing predictable staining characteristics. 2. Review of laboratory policy, "H&E Staining Quality Control Procedure" (Reviewed by the Laboratory Director on 01 /2022) revealed the following: "1. The H&E staining control slide will be made and evaluated by Laboratory technician each day prior to patient testing. 2. The control slide should be stained according to the laboratory H&E staining procedure." The laboratory failed to specify the intended reactivity for Hematoxylin and Eosin (H & E) staining to ensure predictable staining characteristics. 3. Review of, "H&E Quality Control Log" for April 2021-September 2022 revealed dates quality control was performed. Corresponding with the dates, are cells filled with a check mark citing "Good, Fair, Poor". The laboratory failed to provide a legend defining "Good, Fair, Poor" on the H&E quality control log. The laboratory failed to specify the intended reactivity for Hematoxylin and Eosin (H & E) staining to ensure predictable staining characteristics prior to patient testing for 17 of 17 months (April 2021-September 2022). 4. During an interview, in the dermatology office, on 10/14/2022 at 11:28 a.m., the Laboratory Director confirmed the above findings.