Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2129041	08/07/2019
Name of Provider or Supplier	**Street Address, City, State**	
Ut Southwestern Clinical Center At Fort Worth	600 S Main Street, Fort Worth, 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	Entrance and exit conferences were held with the laboratory representative. The survey process was discussed and survey forms were provided. An opportunity for questions and comments was given. Noted deficiency and plans of correction were discussed with the laboratory representative at the entrance and exit conferences. The facility representative was given an opportunity to provide evidence of compliance with the noted deficiency, 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 review of laboratory operator's manuals, laboratory environmental records (10/2017 through 11/2018), and confirmed in interview, the laboratory failed to ensure humidity levels were within the specification requirements for the Linistat

	Linear Stainer and the Thermo HM525NX cryostat instruments for 14 of 14 months. Findings included: 1. Review of the Linistat Linear Stainer operator's manual (A79810100, Issue 4) stated the following in the Environmental Specification section: "Relative Humidity: Max. 80%RH up to 31C Decreasing linearly to 50% RH at 40C" Review of the Thermo HM525NX cryostat operator's manual (388159, Issue 8) stated the following in the Environmental Specifications section: "Relative Humidity: Max. 60% RH up to 35C" 2. Review of the laboratory environmental record titled "Quality Control Record for Mohs Lab: Temperature and Humidity" stated, "Humidity: Must be below 60%". Review of records from 10/2017 through 11/2018 revealed the laboratory failed to document humidity for 14 of 14 months. 3. In an interview on 08 /07/2019 at 1000 hours in the laboratory, the laboratory representative was asked if the humidity levels were monitored. She stated that the laboratory did NOT monitor humidity levels. This confirmed the finding that the laboratory failed to ensure humidity levels were within the specification requirements for the Linistat Linear Stainer and the Thermo HM525NX cryostat instruments. Word Key: Max=Maximum RH=Relative Humidity