Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2108258	03/23/2022
Name of Provider or Supplier	**Street Address, City, State**	
Ut Md Anderson Cancer Center-Tumor Marker Lab	7777 Knight Road, 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	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility representative(s) 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 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 Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: . Based on review of the laboratory's twice annual accuracy verification records for 2020 and 2021, review of the College of American Pathologists (CAP) participant result evaluation and Participant Summary documents for the same interval and staff interview it was determined the laboratory failed to document self-evaluation follow up for 1 of 1 ungraded result as per proficiency testing (PT) agency's requirements. Findings included: 1. Review of the laboratory's twice annual accuracy verification records for 2020 and 2021 revealed the laboratory was using CAP Proficiency Testing program to fulfill this regulatory requirement. 2. Review of the CAP participant result evaluations for 2020 and 2021 revealed the laboratory had one instance of ungraded analyte result without documentation of self-evaluation follow up: Analyte: CA 125 Specimen: TM -06 Event: TM - B 2020 Tumor Markers Grade: See Note [22] 3.

	Review of the CAP Participant Summary document for the above PT event revealed under section "Actions Laboratories Should Take when a PT Result is Not Graded" (page 10): "Code: 22 Exception Reason Code Description: Result is outside the method/instrument reportable range. Action Required: Document the comparison of results to the proper statistics supplied in the participant summary. Verify detection limits. Perform and document the corrective action of any unacceptable results." 4. The laboratory was asked to provide documentation of the follow up action required by the PT agency for the ungraded result and no such documentation was available for review. 5. In an interview on 03/23/2022 at 1115 in the office the laboratory director (as described on submitted Form 209, signed by laboratory director on 03/08/2022), after review of the data, confirmed the findings.