Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2108258	04/12/2018
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 to be in compliance with applicable Conditions of Participation in the CLIA program, and certification 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.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's quality control records from February 2016 to March 2018, and staff interview, it was revealed the laboratory failed to have

	documentation of monitoring the accuracy and precision of chemistry control testing over time. The findings were: 1. A review of the PreciControl Tumor Marker control records from February 2016 to March 2018 revealed the laboratory had documentation of assessing the results of quality control on a daily basis for acceptability. 2. Attempted review of the monthly quality control reports from February 2016 to March 2018 showed the laboratory failed to print and review the Levy Jennings or statistical calculations (mean, standard deviations, and coefficient of variation), which present an overall evaluation of quality control performance, and is a tool used to evaluate the accuracy and precision of controls over time. 3. An interview with the testing person on 04/12/2018 at 1128 hours in the office confirmed the above findings. She stated that she in the process of implementing it.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on a review of five patient reports and interview of facility personnel, it was revealed that the laboratory failed to include the name and physical address of the laboratory on all test reports. Findings were: 1. A review of patient "Follow-Up & Progress Notes" reports used to report the CA-125 test result revealed that on five of five test report forms reviewed, the name and the physical address of the testing facility was not on the report form. 2. An interview of the primary testing person and technical consultant on 04/12/2018 at 1146 hours in the office and following the facility representative's own review of the records, the above findings were confirmed. Key; CA-125- cancer antigen 125
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on review of the laboratory's personnel records and interview, the technical consultant failed to evaluate the competency of all testing personnel as shown by: 1. In review of the laboratory's personnel records, the laboratory had worksheets for evaluation of their staff. The worksheets lacked the following six required components for competency: Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing; Monitoring the recording and reporting of test results; Review of intermediate test results or worksheets, quality control records, proficiency testing results, and

	preventive maintenance records; Direct observation of performance of instrument maintenance and function checks; Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; Assessment of problem solving skills; 2. In interview with the primary testing person on 04/12/2018 at 10/21/2018 hours she stated that she was not aware that CLIA had additional requirements for competency.