Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2108258	11/04/2020
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 at the entrance and exit conferences. The facility representative was 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.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions, laboratory policy and patient records, and confirmed in interview, the laboratory failed to establish and monitor conditions for specimen transport for 1 of 1 test on the Cobas ELecsys CA125. Findings were: 1. Review of the package insert for the Cobas Elecsys CA125 (2020-09, V1.0) under specimen requirements revealed "stable for 8 hours at 20-25 C, 5 days at 2-8 C, and 24 weeks at -20 +/- 5 C." 2. Review of the laboratory policies revealed

	no documentation of the specimen transport requirements for the Cobas Elecsys CA125. 3. Random review of the laboratory records from 2019-2020 revealed no documentation of the specimen conditions during transport for 34 specimens on 10 of 10 days reviewed. 11/2/20 - Acc #1588, 1044, 1354, 1552 10/26/20 - Acc# 1520, 689, 1008, 1135 10/5/20 - Acc#1406, 1531, 1291, 1151 9/28/20 - Acc#650, 521, 1265, 1409 1/27/20 - Acc#1146, 1368, 1680, 1511 1/21/20 - Acc# NRRH0437 12/16/19 - Acc#1647, 542, 569, 1217 11/25/19 - Acc#704, 1466, 1012, 989 9/23/19 - Acc#1489, 1334, 297, 1067 11/14/19 - Acc #144 4. An interview with the laboratory manager on 11/4/20 at 1340 hours in her office confirmed the above findings. She stated that the 'holding laboratory' received the specimen frozen on dry ice. They in turn sent them to her laboratory but no documentation of the temperature during transport is kept.
D5409	PROCEDURE MANUAL CFR(s): 493.1251(e) The laboratory must maintain a copy of each procedure with the dates of initial use and discontinuance as described in 493.1105(a)(2). This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, and staff interview, it was revealed the laboratory failed to document the date when procedures were discontinued for 1 of 1 discontinued procedure reviewed. The findings were: 1. A review of the laboratory's policy manual revealed no documentation of a discontinue date for the policy "Temperature Humidity Record " (origin 02/2016) and removed from use 01/2020. 2. An interview with the technical consultant on 10/1/2020 at 1410 hour confirmed the findings these procedures were not documented with date discontinued in the policy manual.
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 manufacturer's instructions, review of laboratory quality control (QC) policy, review of the laboratory environmental records, and confirmed in interview of facility personnel, the laboratory failed to establish acceptable room temperature limits for quality control testing on the Roche Cobas analyzer for CA125. The findings were: 1. Review of the "PreciControl Tumor marker" under "Storage and Stability" states "Stability of reconstituted control serum is the following: -20 degrees celsius plus or minus 5 degrees for 1 month 20 -25 degrees celsius for 24 hours 2-8 degrees celsius for 2 weeks on the analyzers at 20-25 degrees celsius up to 5 hours Ensure controls are at 20-25 degrees celsius prior to measurement 2. Review of the automatic temperature monitoring system revealed it was set at 18- 25 degrees celsius. 3. A random review of laboratory's temperature monitoring environmental records

	from 01/06/2020 to 11/02/2020, revealed the laboratory used the acceptable room temperature range of 18-25 C in the laboratory for quality control testing for 10 of 10 months. Dates Primary Control 1 Primary control 2 01/06/2020 329582 exp 2020/04 329585 exp 2020/04 04/05/2020 405841 exp 2021/04 405842 exp 2021/04 07/06 /2020 405841 exp 2021/04 405842 exp 2021/04 07/22/2020 405841 exp 2021/04 405842 exp 2021/04 10/26/2020 405841 exp 2021/04 405842 exp 2021/04 11/02 /2020 405841 exp 2021/04 405842 exp 2021/04 4. Random review of the laboratory quality control records and patient test records from January 2020 to October 2020 revealed the laboratory performed quality control using the above lot numbers on the Roche Cobas e 411 chemistry analyzer and analyzed and reported patient testing. (See patient alias list) 5. An interview with facility staff on 11/04/2020 at 1120 hours in the laboratory confirmed the above findings. She agreed that they need to update the room temperature limits.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of the laboratory policies, manufacturer's instructions, calibration verification records from 2018 to 2020, and staff interview, the laboratory failed to have documentation of performing six-month calibration verification for CA125 on the Roche Cobas e 411 chemistry analyzer. The findings were: 1. Review of the laboratory policy Calibration and Verification (approved on 04/03/20717 by the laboratory medical director revealed" The frequency of calibration or calibration verification is at least every six months and after a complete change of reagents that affects the reportable patient range or when QC fails to meet established criteria, after major maintenance or service or when recommended by the manufacturer." 2. A review of the calibration records for the CA125 from 2018 to 2019 revealed it used a 2 point calibration; therefore, calibration verification is required every six months. 3. A review of the laboratory's calibration verification records from 2018 and 2019 revealed the laboratory had no documentation of performing calibration verification every six months on Roche Cobas e 411 chemistry analyzer. 4. Review of the

	CMS116 revealed the laboratory performed 3066 CA125 tests annually. 5. An interview with the facility staff on 11/04/2020 at 11:45 hours in the office confirmed the laboratory did not perform the required calibration verifications.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy, the Cobas quality control package insert, patient records, and staff interview, it was revealed the laboratory failed to provide documentation of establishing quality control ranges for the analyte CA-125 prior to patient testing. The findings were: 1. Review of the laboratory's policy " Quality Control Performance, Review, and Monitoring of Laboratory Controls" under "Establishing Quality Control Statistics" states " Working QC ranges are verified and established for each analytical control by each laboratory Medical director or designee through consideration of the following: a. Observed Mean and SD from trial data consisting ideally of at leas 20 determinations, from different days and shifts if applicable, collected while current controls are seen to fall in the appropriate ranges. This data is used to verify the mean during the evaluation. b. Assay of survey or reference specimens of predetermined target values c. Fixed ranges established as appropriate for the specific analyte. 2. A review of quality control records from 07/01 /2019 to 10/28/2020 revealed 2 lot number changes. Review of the laboratory records revealed no documentation of verifying the acceptable ranges for the lot numbers below. PCTM1 Lot # Expiration date Range 329582 2020/04 23.7 -36.3 405841 2121 /04 31.3 - 47.9 PCTM2 Lot # Expiration date 329585 2020/04 82.2 - 126 405842 2021 /04 87.7 - 134 3. A review random patient records from August 26, 2019 to October 12, 2020, revealed the laboratory performed patient testing. Refer to patient alias list. 4. An interview with the facility staff on 11/04/2020 at 11:45 hours in the office confirmed the findings. She stated the laboratory uses the manufacturer's ranges that are provided by the Cobas package insert.