Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 45D0712392	**(X3) Date Survey Completed** 09/21/2020
Name of Provider or Supplier Texas Ambulatory Surgical Center	**Street Address, City, State** 2505 N Shepherd, 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 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.
D5213	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1) The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program. This STANDARD is not met as evidenced by: Based on a review of the laboratory's American Association of Bioanalysts records for Q2 Nonchemistry 2020 and staff interview, it was revealed the laboratory failed to have documentation of verifying the accuracy of analytes that were not graded by the proficiency testing program. Findings include: 1. A review of the American Association of Bionanlysts results for Q2 Nonchemistry 2020 revealed the following analyte was scored as not graded and had a '?' next to the reported value: D (Rho) Typing specimen #9 American Association of Bioanalysts defines that "? = This score may not truly evaluate performance for this specimen which was not graded because of lack of participant consensus." 2. The laboratory was asked to provide

	documentation of verifying the accuracy of the not graded proficiency testing specimen. No documentation was provided. 3. An interview with testing person #4 (as indicated on the CMS 209 form, signed by the laboratory director on 9/18/20) on 9/21 /20 at 9:35 a.m. in the laboratory, after review of the records, confirmed the above findings.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b) (1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on a review of the laboratory's Refrigerator Temperature log for 2020 and staff interview, it was revealed the laboratory failed to have documentation of performing corrective actions when the refrigerator temperature was documented outside the laboratory's acceptable range for 48 of 48 times from January 2020 to September 2020. Findings include: 1. A review of the laboratory's Refrigerator Temperature log from January 2020 to September 2020 revealed the following: "Proper Temperature Range 36 F - 46 F Procedure: 1. Each day of scheduled cases, please initial the appropriate temperature box. 2. If the temperature is above or below the proper temperature range, adjust the thermostat to the proper temperature 3. If the temperature continues to be outside of the proper range contact the Administrator." 2. Further review of the Refrigerator Temperature log for 2020 revealed the following days where the documented refrigerator temperature was outside the laboratory's acceptable range: Date Recorded Temperature 3/12/20 30 F 3/13/20 32 F 4/24/20 32 F 4/30/20 32 F 5/2/20 30 F 5/8/20 30 F 5/15/20 32 F 5/20/20 32 F 5/21/20 32 F 5/22/20 32 F 5/23/20 34 F 5/25/20 32 F 5/28/20 35 F 5/30/20 34 F 6/4/20 34 F 6/5/20 32 F 6/6 /20 34 F 6/7/20 32 F 6/12/20 32 F 6/13/20 32 F 6/19/20 34 F 6/20/20 34 F 6/25/20 32 F 6/26/20 34 F 6/27/20 32 F 7/2/20 34 F 7/9/20 34 F 7/11/20 34 F 7/16/20 34 F 7/17 /20 34 F 7/18/20 34 F 7/30/20 34 F 7/31/20 34 F 8/6/20 32 F 8/7/20 32 F 8/8/20 34 F 8 /13/20 30 F 8/14/20 34 F 8/15/20 32 F 8/20/20 34 F 8/21/20 32 F 8/22/20 32 F 8/27 /20 34 F 8/28/20 32 F 9/3/20 34 F 9/4/20 34 F 9/12/20 34 F 9/18/20 34 F 3. The laboratory was asked to provide documentation of performing corrective actions when the refrigerator temperature was outside of the acceptable range. No documentation was provided. 4. An interview with testing person #5 (as indicated on the CMS 209 form, signed by the laboratory director on 9/18/20) on 9/21/20 at 10:25 a.m. in the laboratory, after review of the records, confirmed the above findings.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The

	laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on a review of the laboratory's quality assurance records, a review of the laboratory's Refrigerator Temperature logs, and staff interview, it was revealed the laboratory's quality assurance plan failed to identify and correct problems in analytic systems. Findings include: 1. The laboratory failed to have documentation of performing corrective actions when the refrigerator temperature was documented outside the laboratory's acceptable range (refer to D5781).