Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0718803	03/25/2021
Name of Provider or Supplier	**Street Address, City, State**	
Texas Avenue Medical Clinic	1703 East 29th St, Bryan, 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
D1000	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(c) Certificate of waiver tests. A laboratory may qualify for a certificate of waiver under section 353 of the PHS Act if it restricts the tests that it performs to one or more of the following tests or examinations (or additional tests added to this list as provided under paragraph (d) of this section) and no others: (1) Dipstick or Tablet Reagent Urinalysis (non-automated) for the following: (i) Bilirubin; (ii) Glucose; (iii) Hemoglobin; (iv) Ketone; (v) Leukocytes; (vi) Nitrite; (vii) pH; (viii) Protein; (ix) Specific gravity; and (x) Urobilinogen. (2) Fecal occult blood; (3) Ovulation tests-visual color comparison tests for human luteinizing hormone; (4) Urine pregnancy tests - visual color comparison tests; (5) Erythrocyte sedimentation rate-non-automated; (6) Hemoglobin-copper sulfate-non-automated; (7) Blood glucose by glucose monitoring devices cleared by the FDA specifically for home use; (8) Spun microhematocrit; and (9) Hemoglobin by single analyte instruments with self-contained or component features to perform specimen/reagent interaction, providing direct measurement and readout. This STANDARD is not met as evidenced by: I. Based on review of manufacturer's instructions, observation, and interview, the laboratory failed to follow manufacturer's instructions for the glucose monitoring of diabetic patients for home use only using the Contour Next blood glucose meter. Findings follow. 1. Review of the Contour Next User Guide under Indications for Use stated, "the Contour Next blood glucose monitoring system is an over-the-counter device utilized by persons with diabetes in home settings for the quantitative measurement of glucose in whole blood, and is for single-patient use only, and should not be shared." 2. Surveyor observed on March 25, 2021 the Contour Next glucose monitor in the drawer in the hall laboratory. 3. Interview with testing personnel #2, on the CMS Form 209, on March 25, 2021 at 1410 hours in the hall laboratory confirmed the Contour Next was the glucose monitor in use in the clinic. II. Based on review of observation, manufacturer's instructions, and interview, the laboratory failed to follow

	manufacturer's instructions by using expired test strips for the Contour Next blood glucose meter. Findings follow. 1. Surveyor observed on March 25, 2021 the open vial of Contour Next blood glucose strips for self-testing, Lot DWBDPEB51B, located in the drawer of the hall laboratory had an expiration date of 04/30/2020. 2. Interview with testing personnel #2, on the CMS Form 209, on March 25, 2021 at 1410 hours in the hall laboratory confirmed the Contour Next blood glucose test strips were the strips currently in use in the laboratory.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of the laboratory's American Proficiency Testing (API) proficiency testing (PT) records, and confirmed in interview of facility personnel, the laboratory failed to provide documentation of 2 of 6 attestation statements being signed by those who were required to sign them. The findings were: 1. Review of API's attestation statement form 2019 (events 1, 2, and 3) and 2020 (events 1, 2, 3) stated, "Testing personnel and the laboratory director must physically sign an attestation statement for all PT results, and retain the signed statement (or a copy) for a minimum of 2 years. Either the attestation statement below or a printed copy of the form provided online can be used for this purpose." 2. Review of the laboratory's API proficiency testing records from 2019 (events 1, 2, and 3) and 2020 (events 1, 2, and 3) found the following attestation statements were not signed: 2019 (event 1) not signed by laboratory director or testing person 2020 (event 3) not signed by laboratory director 3. An interview with testing personnel #1 (as listed on Form CMS-209) at 15:30 hours in the office confirmed the findings
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions, test reports, and interview, the laboratory failed to redact the result, or confirm test results for "marks" on the Complete Blood Count test report using the Sysmex XN-330 hematology analyzer. Findings follow. 1. Review of the Sysmex XN-330 Basic Operation manual, June 2017, under "5.11.2 Display of analysis result data" starting on page 5-22 stated, "When an analysis result could not be obtained due an error or other problem, the result is masked. When as analysis result is determined to be abnormal, a mark appears." Under Marks the * (asterisk) is shown with the Meaning of "low reliability." 2. Review of 1 of 1 patient test reports with a "mark" sample number 7 tested on 02/05 /2021 with the * asterisks on the test results for PLT (platelets) and MPV (mean platelet volume). 3. Interview with testing personnel #2, on the CMS form 209, on

	March 25, 2021 at 1705 hours in the conference room confirmed the physician looks at the test report and they send the sample to the reference lab. The patient was a self-pay patient and cancelled the additional lab work. Interview with testing personnel #1 on March 25, 2021 at 1710 hours in the conference room agreed to send an example of a patient test report with a "mark" sent to a reference lab. No examples were received as of report date April 5, 2021.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of the verification of performance specifications, and interview, the laboratory failed to verify the normal patient reference range for the Complete Blood Count using the Sysmex XN-330 hematology analyzer. Findings follow. 1. Review of the Sysmex XN-330 verifications of performance specifications performed at installation on Jan 8 & 9, 2020 showed no documentation of the verification of the normal patient reference range. The normal reference range was requested but not provided. 2. Interview with testing personnel #1, on the CMS Form 209, on March 25, 2021 at 1700 hours acknowledged she had no idea whether the verification of the normal reference range had been verified.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on review of the maintenance logs, observation and interview, the laboratory failed to document maintenance on the Sysmex XN-330 hematology analyzer used to test Complete Blood Counts for 5 of 15 months reviewed. Findings follow. 1. Review of the XN-330 Maintenance log from Jan 2020 - current, showed no logs for: a. Oct 2020, b. Nov 2020, c. Dec 2020, d. Feb 2021, and e. March 2021. 2. Surveyor observed on March 25, 2021 at 1550 hours in the conference room, the January 2021 XN-330 Maintenance log showed the tech initials were of the same handwriting for maintenance performed by 5 different testing personnel. 3. Interview with testing personnel #1, on the CMS Form 209, on March 25, 2021 at 1550 hours in the conference room confirmed there were missing maintenance logs, and no current maintenance log for March 2021.