Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0482164	03/30/2023
Name of Provider or Supplier	**Street Address, City, State**	
Tijerina Urology Clinic	811 East Austin Street, Paris, 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	An onsite survey conducted 03/30/2023 found the laboratory in compliance with 42 CFR Part 493, Requirements for Laboratories.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on a review of reagent instructions for use, laboratory policy, quality control documents, the Centers for Medicare and Medicaid (CMS) form 116, and confirmed in an interview, the laboratory failed to have a policy for the establishment of new lot quality control means and ranges for PSA testing on the NanoEntek Frend system for one of one QC lot in use for eleven months from April 2022 to March 2023. The findings include: 1. Review of the "FREND PSA Plus" instructions for use, section "External quality control testing", had the following statement: "Individual laboratory policy will dictate exactly which control materials and lot number should be run, the frequency which controls are to be tested, criteria for acceptance of the results and required corrective action to be taken if results do not meet laboratory criteria .... Refer to your laboratory policies on how to determine the acceptability of external controls." 2. Review of the laboratory policy titled "Quality Control Program" stated the following: "Acceptable results for the controls performed must fall within range established in house by using commercial controls specified." 3. Review of laboratory quality control (QC) documents, provided by Applied Becker Consulting on 4/7/2022, and monthly QC worksheets had the following discrepant information: QC Level 1: Lot 2008122A, Exp 10/31/2023 Mean - 1.391 ng/mL, SD 0.063 2SD QC range provided: 1.26 - 1.52 ng/mL QC Range in use: 1.20 - 1.50 ng/mL QC Level 2: Lot

	2008123A, Exp 10/31/2023 Mean 12.701 ng/mL, SD 0.564 2SD QC range provided: 11.57 - 13.83 QC range in use: 11.0 - 14.39 ng/mL Surveyor queried where the ranges on the QC worksheets came from; the technical consultant 2 (TC2) stated the laboratory utilized a 3SD range because the 2SD range was too tight. Surveyor queried for the laboratory policy used in determining the acceptable range used in determining if QC was acceptable, and none was provided. 4. Review of laboratory QC records from April to March 2023 had the following QC documented outside of the 2SD range provided. 4/14/2022 Machine B - QC level 1 - 1.25 ng/mL Machine C - QC level 1 - 1.20 ng/mL 6/9/2022 Machine C - QC level 2 - 13.94 ng/mL 7/7/2022 Machine C - QC level 2 - 13.94 ng/mL 8/4/2022 Machine B - QC level 2 - 14.00 ng /mL 9/8/2022 Machine B - QC level 2 - 13.90 ng/mL Machine C - QC level 2 - 14.05 ng/mL 10/6/2022 Machine B - QC level 2 - 14.36 ng/mL Machine C - QC level 2 - 14.16 ng/mL 1/13/2022 Machine B - QC level 2 - 14.27 ng/mL Machine C - QC level 2 - 14.24 ng/mL 3/9/2023 Machine B - QC level 2 - 14.34 ng/mL Machine C - QC level 2 - 14.04 ng/mL 5. Review of the CMS116 section VII "Non-Waived Testing" listed the annual test volume for routine chemistry at 2,400. 6. In an interview on 3/30 /2023 at 13:40, in the conference room, TC2 confirmed that the laboratory did not have a policy in place for the establishment and acceptability of ranges for new lot QC. KEY: PSA - prostate-specific antigen
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 surveyor observation, review of laboratory documents, and confirmed in an interview, the laboratory failed to have a system in place to monitor the accuracy and precision of quality control (QC) materials over time for two of two analyzers in use for PSA testing in 2022. The findings include: 1. In a tour of the laboratory on 3/30 /2023 at 10:00 hours, the surveyor noted two NanoEntek FREND analyzers used for PSA testing. 2. Review of laboratory quality control documents did not include a mechanism to review QC for accuracy and precision over time for the two analyzers. Surveyor queried if documentation was available, and none was provided. 3. In an interview on 3/30/2023 at 13:30 hours, in the conference room, the technical consultant 2 (TC2) confirmed that the laboratory did not have a mechanism in place to monitor QC for accuracy and precision over time for the two NanoEntek FREND analyzers in 2022. KEY: PSA - prostate-specific antigen