Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0482164	05/22/2019
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
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 review of laboratory documentation for 2017, 2018 and 2019 confirmed by staff interview, laboratory personnel failed to follow written procedures for temperature monitoring, quality control performance and policy review. I. (a) The laboratory procedure manual states: "...the laboratory refrigerator will be between 36-46 degrees F. If the temperatures/humidity are outside these ranges, corective action will be taken (i.e. adjusted temperature control knob and check testing supplies for deterioration) and documentation of the troubleshooting will be kept on Temperature /Troubleshooting Chart." (Laboratory Procedure Manual, Quality Assessment (QA) Program, I. QA Monitors, part A) (b) Review of laboratory refrigerator temperature monitoring documentation for 2018 and 2019 revealed the following temperatures outside acceptable range: Date Temperature Action noted 11-13-2018 30 F Adjusted Temperature 01-23-2019 31 F Adjusted Temperature 01-29-2019 31 F Adjusted Temperature 02-19-2019 32 F Adjusted Temperature 03-06-2019 30 F Adjusted Temperature (temperatures in degrees Fahrenheit) (c) The Troubleshooting section of the chart showed no indication that testing supplies were examined for deterioration when recorded temperatures were out of range. (d) In an interview at the site on 05-22-2019, laboratory technical consultant 2 (CMS form 209) confirmed that the temperatures in question were out of acceptable range, and further stated that testing personnel had recorded the temperatures without documenting whether testing supplies had been affected. II. (a) The laboratory procedure manual states: "PSA (prostate specific antigen) control failures: Specimens are to be held for one week. If

	there is a control failure, spot testing on the specimens will be done from the last successful quality control test to determine when the problem occurred." (Laboratory Procedure Manual, Quality Assessment (QA) Program, I. QA Monitors, part E) (b) The quality control (QC) log sheet for Level 2 QC, lot number 1706091A, expiration date 05-15-2019, performed 04-15-2019 shows a result on instrument B of 11.01 nanograms per mililiter (ng/mL). The acceptable range listed on the form is 11.02-14.12. No corrective action was noted in the section designated on the reporting form. (c) In an interview at the site on 05-16-2017, laboratory technical consultant 2 acknowledged that applicable policy had not been followed for the out of range QC result. III. The laboratory procedure manual states: "Annual Policies and Procedures Review In maintaining compliance with state and federal guidelines, all policies and procedures are reviewed at least annually by the Laboratory Medical Director. Changes made are initialed and dated by the Medical Director prior to being placed into routine use. Testing personnel are made aware of changes that affect any phase of the life of a sample. These notifications are made in writing with documented acknowledgement from all Testing Personnel. By signing below, the Medical Laboratory Director attests that he has issued and has approved the policies and procedures currently in use for this Laboratory." (Laboratory Procedure Manual, Annual Policies and Procedures Review) Examination of the review form showed the latest dated signature by the Medical Laboratory Director (laboratory director, CMS form 209) to be 08-20-2017. In an interview at the site on 05-22-2019, technical consultant 2 confirmed the signature date. .
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: . Based on review of laboratory QC documentation for 2017, 2018 and 2019 using the NanoEntek FREND system, the result of one month's quality control fell outside acceptable range. (refer to D5401 I) The laboratory tests an average of 233 patients per month for PSA using this system.