

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 45D0482164	<b>(X3) Date Survey Completed</b> 11/05/2021
<b>Name of Provider or Supplier</b> Tijerina Urology Clinic	<b>Street Address, City, State</b> 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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	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.
<b>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory's submitted CMS 209 form, a review of the laboratory's personnel records, a review of the laboratory's policies, and staff interview, it was revealed that the laboratory failed to have documentation of performing a competency assessment for one of two technical consultants. Findings include: 1. A review of the laboratory's submitted CMS 209 form (signed by the laboratory director on 11/5/21) revealed the laboratory identified two technical consultants. 2. A review of the laboratory's personnel records revealed the laboratory failed to have documentation of performing a competency assessment for technical consultant #2. 3. A review of the laboratory's policies revealed that the laboratory did</p>

not have a policy that defined how often the competency of the technical consultant had to be assessed. 4. An interview with technical consultant #2 (as indicated on the CMS 209 form) on 11/5/21 at 8:35 a.m. in the office revealed the laboratory did not assess the competency of the technical consultant. This confirmed the above findings.

**D5403**

**PROCEDURE MANUAL**  
CFR(s): 493.1251(b)

The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:

Based on a review of the laboratory's policies, the laboratory's records, and staff interview, it was revealed that the laboratory's policy failed to define the acceptability criteria used for assessing seven of seven analyzer comparisons done in 2019, 2020, and 2021 between the two Frenel analyzers for PSA (prostate specific antigen) testing. Findings include: 1. A review of the laboratory's policy titled 'Quality Assessment Program' revealed the following: "Twice a year the two machines used for PSA will be compared to each other to assure accuracy. Patient samples will be run on both machines and results compared." 2. A review of the laboratory's records revealed the laboratory performed seven analyzer comparisons between the two Frenel analyzers (serial numbers: F100140204-007 and F100160505-013) on the following dates: 9/9/2019 2/25/20 3/11/20 6/30/20 4/22/21 5/27/21 11/4/21 3. Further review of the laboratory's records revealed there was no documentation of the laboratory's acceptability criteria used to assess the analyzer comparisons. 4. An interview with technical consultant #2 (as indicated on the CMS 209 form) on 11/5/21 at 9:00 a.m. in the office, after review of the records, confirmed the above findings.

**D5445**

**CONTROL PROCEDURES**  
CFR(s): 493.1256(d)(1)(2)(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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when

they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on a review of the laboratory's IQCP (Individualized Quality Control Plan) for the two FrenD analyzers, the laboratory's quality control records from 2020 and 2021, and staff interview, it was revealed that the laboratory failed to have documentation of running the quality controls on the two FrenD analyzers at the frequency established by the IQCP for eight of sixteen months from March 2020 to July 2021. Findings include: 1. A review of the laboratory's IQCP for the two FrenD analyzers used for PSA (prostate specific antigen) testing revealed the laboratory tested the CLINIQA Liquid Control Material (levels 1 and 2) every 30 days or with new shipment/lot of testing materials. 2. A review of the laboratory's quality control (QC) records from March 2020 to July 2021 revealed the laboratory ran the quality controls beyond the frequency of 30 days for the following 8 months: QC performed: 3/11/20 Next time QC performed: 5/7/20 Time elapsed between QC runs: 58 days QC performed: 5/7/20 Next time QC performed: 6/25/20 Time elapsed between QC runs: 50 days QC performed: 7/30/20 Next time QC performed: 9/14/20 Time elapsed between QC runs: 47 days QC performed: 9/14/20 Next time QC performed: 10/26/20 Time elapsed between QC runs: 43 days QC performed: 10/26/20 Next time QC performed: 12/2/20 Time elapsed between QC runs: 38 days QC performed: 12/2/20 Next time QC performed: 1/25/21 Time elapsed between QC runs: 55 days QC performed: 1/25/21 Next time QC performed: 3/4/21 Time elapsed between QC runs: 39 days QC performed: 5/27/21 Next time QC performed: 7/8/21 Time elapsed between QC runs: 43 days 3. A review of the laboratory's submitted CMS 116 application revealed the laboratory estimated 8,800 PSA tests were performed annually. 4. An interview with technical consultant #2 (as indicated on the CMS 209 form) on 11/5/21 at 10:20 a.m. in the office, after review of the records, confirmed the above findings.

**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 a review of the laboratory's policies, the manufacturer's instructions for the CLINIQA Liquid QC, the quality control records from March 2020 to October 2021, and staff interview, it was revealed that the laboratory failed to establish its own means and acceptable ranges for four of four lot numbers of QC material used for PSA (prostate specific antigen) testing on the two FrenD analyzers. Findings include:

1. A review of the laboratory's policy titled 'Quality Assessment Program' revealed the following: "PSA controls are run according to NanoEntek Frend guidelines." 2. A review of the manufacturer's instructions for the CLINIQA Liquid QC (ref. 94102, 8/24/18) revealed the following: "The expected range of the mean is provided to assist the laboratory until it has established its own mean and statistical deviation. It is considered good laboratory practice for each laboratory to establish its own mean and standard deviation for its test methods. The indicated mean and expected rang of the mean should serve as a guide in assessing the performance of each test method." 3. A review of the laboratory's quality control records from March 2020 to October 2021, revealed the laboratory was using the manufacturers ranges for the following 4 lot numbers of CLINIQA Liquid quality controls: Level 1: 1706090A 2008122A Level 2: 1706091A 2008123A 4. An interview with technical consultant #2 (as indicated on the CMS 209 form) on 11/5/21 at 13:25 a.m. in the office, after review of the records, confirmed the above findings.

**D6054**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:  
Based on a review of the laboratory's submitted CMS 209 form, review of the laboratory's personnel files, and staff interview, it was revealed that the technical consultant failed to perform a competency assessment in 2019 and 2020 on one of four testing personnel for moderate complexity testing. Findings include: 1. A review of the laboratory's submitted CMS 209 form (signed by the laboratory director on 11/5/21), revealed the laboratory identified four testing personnel. 2. A review of the laboratory's personnel records revealed that there was no documentation of the technical consultant performing a competency assessment in 2019 and 2020 for the following testing personnel: Testing person #4 3. An interview with technical consultant #2 (as indicated on the CMS 209 form) on 11/5/21 at 8:35 a.m. in the office, after review of the records, confirmed the above findings.