

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D0278612	<b>(X3) Date Survey Completed</b>  10/12/2020
<b>Name of Provider or Supplier</b>  Urology Center Of Florida Pa	<b>Street Address, City, State</b>  550 Sw 3rd St Ste 305, Pompano Beach, FL	
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>	<p>A recertification survey conducted on 10/05/2020 -10/12/2020, found that Urology Center of Florida PA clinical laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. Immediate Jeopardy (IJ) was identified during the survey. The laboratory failed to complete the validation on a moderate complexity Frennd System instrument for prostate-specific antigen (PSA) and Testosterone before it began patient testing on 11/19/19 and through out 10/9/2020. (see 5421) The laboratory failed to document the performance of daily quality control (QC) Cartridges and Monthly External QC CLINIQA level 1 and 2 runs on the unvalidated Frennd System instrument for PSA and Testosterone for the period of time mentioned above.(see 5441) The laboratory failed to follow and document analytic quality assessments(QA) which resulted in failure to review quality controls and ensure the validation of the Frennd system instrument from Nov 19, 2019 to Oct 9, 2020.(see 5791) (see 5400) The following are IJ Conditions: 5400- Analytic Systems The following Conditions were not met: 5200- General Laboratory Systems 6063- Laboratory Testing Personnel 6076- Laboratory Director The laboratory was notified of IJ level deficiencies on 10/09/2020 at 4:52 pm.</p>
<b>D3009</b>	<p><b>FACILITIES</b> CFR(s): 493.1101(c)</p> <p>The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interviews, the laboratory failed to have a CLIA Certificate of Compliance that included the subspecialty of Endocrinology for Testosterone from January 1, 2019 to October 9, 2020. Findings Included: Review of the CMS-116 report revealed the subspecialty of Endocrinology was not added. Review of Patient Report logs revealed patient testing for Testosterone from 1/1/2019 to 10/09/2020. During an interview on 10/12/2020 at 10:05 am, the office manager</p>

confirmed the lab was testing for Testosterone without the subspecialty of Endocrinology in CLIA Certificate of Compliance from January 1, 2019 to October 9, 2020.

**D5200**

**GENERAL LABORATORY SYSTEMS**

CFR(s): 493.1230

Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed.

This CONDITION is not met as evidenced by:

This a repeated deficiency from 8/21/2018. Based on record review and interview, the laboratory failed to follow their competency assessment plan and failed to perform annual competency assessments for 1(TP#E) out of 5 testing personnel (TP) in 2019 and 2020. (See 5209) Based on record review and interview, the laboratory failed to perform endocrinology proficiency testing (PT) for Testosterone twice annually to verify to accuracy of testing in 2019 and 2020. (see 5217) This is a repeated deficiency from 8/21/2018. Based on record review and interview, the laboratory failed to follow their quality assessment (QA) procedure and perform a QA checklist monthly from June 2019 to September 2020. (see 5291)

**D5209**

**PERSONNEL COMPETENCY ASSESSMENT POLICIES**

CFR(s): 493.1235

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.

This STANDARD is not met as evidenced by:

This a repeated deficiency from 8/21/2018. Based on record review and interview, the laboratory failed to follow their competency assessment plan and perform annual competency assessments for 1(TP#E) out of 5 testing personnel (TP) in 2019 and 2020. Findings Included: Review of the Laboratory Training Procedure stated "there will be an annual employee evaluation of laboratory personnel." Review of CMS-209 Laboratory Personnel Form indicated TP#E is a testing person. Review of Personnel Competency Assessment folder lacked documentation of annual competency assessments done for TP#E in 2019 and 2020. During an interview on 10/12/2020 at 10:05am, the office manager confirmed annual competency assessments were not done for TP#E in 2019 and 2020.

**D5217**

**EVALUATION OF PROFICIENCY TESTING PERFORMANCE**

CFR(s): 493.1236(c)(1)

At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.

	<p>This STANDARD is not met as evidenced by:  This is a repeated deficiency from 8/21/18. Based on record review and interview, the laboratory failed to perform endocrinology proficiency testing (PT) for Testosterone twice annually to verify the accuracy of testing in 2019 and 2020. Findings Included: Review of Patient Report Logs revealed that Testosterone testing had been performed on patients since 2019. Review of American Proficiency Institute folder revealed PT was not performed twice annually in 2019 and 2020 for Testosterone. There was no documentation of Testosterone enrollment for the year of 2019 and 2020. During an interview on 10/12/2020 at 10:15am, the office manager confirmed PT was not performed twice annually for Testosterone in 2019 and 2020.</p>
<p><b>D5221</b></p>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE  CFR(s): 493.1236(d)</p> <p>All proficiency testing evaluation and verification activities must be documented.</p> <p>This STANDARD is not met as evidenced by:  Based on record review and interview, the laboratory was enrolled in American Proficiency Institute (API) proficiency testing (PT) and failed to have documentation for the 0% received in 1st event of 2019 and 2nd event of 2020 for prostate-specific antigen (PSA). Findings Included: Review of API proficiency folder revealed there was no documentation of corrective action and test reports for the 0% received in for 1st PT event of 2019 and 2nd PT event of 2020 for PSA. During an interview on 10/12/2020 at 10:05 am, the office manager confirmed there was no documentation for the 1st PT event of 2019 and 2nd PT event of 2020 for PSA.</p>
<p><b>D5291</b></p>	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT  CFR(s): 493.1239(a)</p> <p>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 general laboratory systems requirements specified at 493.1231 through 493.1236.</p> <p>This STANDARD is not met as evidenced by:  This is a repeated deficiency form 8/21/2018. Based on record review and interview, the laboratory failed to follow their quality assessment (QA) procedure and perform a QA checklist monthly from June 2019 to September 2020. Findings Included: Review of QA procedure revealed the laboratory will perform a system quality assessment each month by the laboratory director and refer to QA checklist. Review of the QA Checklist folder revealed no documentation of QA checklists performed from June 2019-September 2020. During an interview on 10/12/2020 at 10:05am, the office manager confirmed QA checklist were not done from June 2019 to September 2020.</p>
<p><b>D5400</b></p>	<p>ANALYTIC SYSTEMS  CFR(s): 493.1250</p> <p>Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the</p>

overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.

This CONDITION is not met as evidenced by:

Based on record review and interview, the laboratory failed to complete a validation on a moderate complexity FrenD System instrument for prostate-specific antigen (PSA) and Testosterone before it began patient testing on 11/19/19 to 10/9/2020. (see 5421) Based on record review and interview, the laboratory failed to document the performance of daily quality control (QC) Cartridges and Monthly External QC CLINIQA level 1 and 2 runs on the unvalidated FrenD System instrument for PSA and Testosterone from November 19, 2019 - October 9, 2020. (See 5441) Based on record review and interview, the laboratory failed to follow and document analytic quality assessment (QA) which resulted in failure to review quality controls and ensure the validation of the FrenD system instrument from Nov.19, 2019 to Oct 9, 2020. (see 5291)

**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 record review and interview, the laboratory failed to complete a validation on a moderate complexity FrenD System instrument for prostate-specific antigen (PSA) and Testosterone before it began patient testing on 11/19/19 to 10/9/2020. Findings Included: Review of Verification of Reportable Range and Calibration for PSA worksheet revealed no documentation for starting date of testing. The value of Vial C was not documented. There was no documentation to verify the reportable ranges matching Linearity Kit. Review of verification of Reportable Range and Calibration for testosterone revealed no documentation for starting date of testing. The value of Vial C was not documented. There was no documentation to verify the reportable ranges matching Linearity Kit. Review Verification of Accuracy and Precision for PSA and Testosterone form revealed the mean levels 1 and 2 for external quality controls were not documented for PSA and Testosterone. Review of FrenD System manual states that to receive the validation report you must submit worksheets by fax or email to the company headquarters. There was no documentation the lab had submitted the worksheets to the company for the full validation report as of 10/9 /2020. A review of patient reports revealed the FrenD System instrument had begun patient testing from 11/19/19 to 10/9/2020. During an interview on 10/12/2020 at 10:05am, the office manager confirmed the validation was not complete for the FrenD system instrument for PSA and Testosterone as of 10/9 /2020 and was in current use for patient testing.

**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 record review and interview, the laboratory failed to document the performance of daily quality control (QC) Cartridges and Monthly External QC CLINIQA level 1 and 2 runs on the unvalidated FrenD System instrument for PSA and Testosterone from November 19, 2019 - October 2020. Findings Included: Review of FrenD QC Requirement manual revealed QC is performed daily for assayed patient samples . The QC must pass the three components: Laser Power, Alignment, Mechanical Integrity (Calculate Ratio) . For External QC test use CLINIQA's external solution level 1 and level 2 and perform monthly. Review of Quality Control Log for Testosterone and PSA revealed no documentation of lot numbers and range values: high, mean and low for external QC level 1 and 2 from 11/19/2019 to 10/9/2020. Incomplete values were written for external QC level 1 and 2 from 11/19/19 to 12/30 /19. No external QC level 1 and 2 were documented from Jan. to Oct. 9, 2020. Daily QC lot numbers and three components were not documented to determine if QC passed from Jan. to Oct. 9, 2020. No documentation of a review of QC and external QC by the laboratory director from 11/19/2019 to 10/9/2020. Daily QC were missing instrument print outs from Nov. 19, 2019 to Dec. 31, 2019 to determine if QC passed. During an interview on 10/12/2020 at 10:05am, the office manager confirmed daily QC and monthly external QC level 1 and 2 were not documented to ensure the performance.

**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 record review and interview, the laboratory failed to follow and document analytic quality assessment (QA) which resulted in failure to review quality controls and ensure the validation of the FrenD system instrument from Nov19, 2019 to Oct 9, 2020. Findings Included: Review of QA procedure revealed the laboratory will perform a system quality assessment each month by the laboratory director and refer to QA checklist. Review of Analytic systems QA Checklist revealed no documentation of quality control review and validation review of the FrenD system instrument from November 2019 to October 9, 2020. During an interview on 10/12 /2020 at 10:05am, the office manager confirmed no documentation and review of

	<p>quality controls and validation for the Frennd instrument in the QA checklist from November 2019 to October 9, 2020.</p>
<p><b>D6063</b></p>	<p><b>LABORATORY TESTING PERSONNEL</b> CFR(s): 493.1421</p> <p>The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.</p> <p>This CONDITION is not met as evidenced by: Based on record review and interview, the laboratory failed to provide diplomas for 2 (TP#D and TP#E) out of 5 testing personnel (TP) that were performing moderate complexity testing. (see 6065)</p>
<p><b>D6065</b></p>	<p><b>TESTING PERSONNEL QUALIFICATIONS</b> CFR(s): 493.1423(b)(1)(2)(3)(4)(i)</p> <p>(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to provide diplomas for 2 (TP#D and TP#E) out of 5 testing personnel (TP) that were performing moderate complexity testing. Findings Included: Review of CMS-209 Laboratory Personnel Form indicated TP#D and TP#E are testing persons. Review of Employee Folders revealed TP#D and TP#E do not have documentation of diplomas. During an interview on 10/12/2020 at 10:05am, the office manager confirmed TP#D and TP#E did not have their diplomas on file. The office manager stated the dipolmas would be provided on 10/12/2020 and it was not recieved.</p>
<p><b>D6076</b></p>	<p><b>LABORATORY DIRECTOR</b> CFR(s): 493.1441</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on record review and interview, the laboratory director failed to ensure the validation the Frennd system instrument before patient testing from Nov 19, 2019 to</p>

	<p>Oct 9, 2020. (see 6086) This a repeated deficiency from 8/21/2018. Based on record review and interview, the laboratory director failed to ensure the laboratory was following their Quality Assurance (QA) procedure and performing QA checklists monthly. (see 6094) This is a repeat deficiency from 8/21/2018. Based on record review and interview, the laboratory director failed to ensure the laboratory followed their competency assessment plan and perform annual competency assessments for 1 (TP#E) out of 5 testing personnel (TP) for 2019 and 2020. (see 6103)</p>
<p><b>D6086</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b>  CFR(s): 493.1445(e)(3)(ii)</p> <p>The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method.</p> <p>This STANDARD is not met as evidenced by:  Based on record review and interview, the laboratory director failed to ensure the validation the Frened system instrument before patient testing from Nov. 19, 2019 to Oct. 9, 2020. Findings Included: -Refer 5423</p>
<p><b>D6094</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b>  CFR(s): 493.1445(e)(5)</p> <p>The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.</p> <p>This STANDARD is not met as evidenced by:  This a repeated deficiency from 8/21/2018. Based on record review and interview, the laboratory director failed to ensure the laboratory was following their Quality Assurance (QA) procedure and performing QA checklists monthly. Findings Included: Refer to 5291 Refer to 5791</p>
<p><b>D6103</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b>  CFR(s): 493.1445(e)(13)</p> <p>The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills.</p> <p>This STANDARD is not met as evidenced by:  This a repeated deficiency from 8/21/2018. Based on record review and interview, the laboratory director failed to ensure the laboratory followed their competency assessment plan and perform annual competency assessments for 1 (TP#E) out of 5 testing personnel (TP) for 2019 and 2020. Finding Included: -Refer to 5209</p>