Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D0984062	(X3) Date Survey Completed 05/03/2019
Name of Provider or Supplier Advanced Urology	Street Address, City, State 4959 Golf Rd, Skokie, IL	

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
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. This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and interviews with the laboratory director (LD) and testing personnel (TP1); the laboratory failed to verify the accuracy of Histopathology tests and procedures it performs during the years of 2017 through 2019. Findings Include: 1. The procedures manual, the College of American Pathologists (CAP) proficiency test (PT) records, and the laboratory's worksheets/tests logs for the Fluorescence In-Situ Hybridization (FISH) test and cytology were reviewed. 2. The manual states the following procedures to fulfill the twice annual verification requirements for the Urine cytology and FISH tests: *Enroll into the CAP-PT program for FISH testing; and *Every 6 months, randomly select 10 Urine cytology slides to be re-read by another CLIA certified Pathologist. 3. The PT reports and test logs revealed the following: *The laboratory ran and submitted PT results for Event #1 of 2018, but not for the years of 2017 and 2019 and showed no participation during Event #2 of 2018. *The Urine cytology 10 slide re-read was completed for 2017, but not for 2018 and 2019. 4. On a recertification survey conducted on 05/03 /2019 at 2:30 PM, the LD and TP confirmed the above findings.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 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

	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, manufacturer's instructions, and an interviews with the testing personnel (TP1) and laboratory director (LD); the laboratory failed to performs nonwaived testing that meet the applicable analytic systems requiremennts for endocrinology testing. Findings include: 1. The laboratory failed to follow written quality control procedures. See D5401. 2. The laboratory failed to follow the manufacturer's instructions. See D5411. 3. The laboratory failed to perform calibration verifications every 6 months. See D5437.
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 record review and an interview with the testing personnel (TP1); the laboratory failed to follow written quality control (QC) procedures for the Prostrate Specific Antigen (PSA) and Testosterone (TEST) tests performed, affecting 513 test results. Findings include: 1. The laboratory procedures manual, QC and patient test records from July of 2017 through April of 2019 were reviewed. 2. The laboratory's Individual Quality Control Plan (IQCP) reduced the frequency of running controls for both PSA and TEST, from each day of patient testing to once every week. 3. The PSA and TEST QC records showed the controls for PSA and TEST controls were not performed on 39 out of 99 weeks patients were tested. 4. Further, review revealed 513 tests were performed during the 39 weeks no PSA controls were ran. 5. On a recertification survey conducted on 05/03/2019 at 2:30 PM, the TP1 confirmed the above 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 record review, manufacturer's instructions, and an interview with the testing personnel (TP1); the laboratory failed to follow the manufacturer's instructions for the Testosterone (TEST) tests performed during the years of 2017 through 2019. Findings include: 1. The manufacturer's instructions, quality control (QC) and patient test records from July of 2017 through April of 2019 were reviewed. 2. The manufacturer requires the laboratory to perform calibrations for the Testosterone test every 15 days. 3. The QC records of TEST revealed calibrations were performed once per month and

	with each new kit lot. 4. On a recertification survey conducted on 05/03/2019 at 2:30 PM, the TP1 confirmed the above findings.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on record review, manufacturer's instructions, and an interview with the testing personnel (TP1); the laboratory failed to follow the manufacturer's test system instructions to perform calibration verifications every 6 months for the Prostate Specific Antigen (PSA) and Testosterone (TEST) tests performed during the years of 2017 through 2019. Findings include: 1. The procedures manual, manufacturer's instruction, and quality control records were reviewed. 2. The manufacturer requires calibration verification procedures to be performed every 6 months for PSA and TEST testing. 3. Records revealed calibration verifications were performed on the following dates: * PSA - 01/04/2017 (date of installation) and 03/18/2019 * TEST - 03/02/2017 and 03/21/2019 4. On a recertification survey conducted on 05/03/2019 at 2:30 PM, the TP1 stated that they were unaware the calibrations needed to be performed every 6 months.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on record review, the manufacturer's instructions, and an interview with testing personnel (TP1); the laboratory director (LD) failed to provides overall management and direction in accordance with 493.1407 in the subspecialty of Endocrinology. Findings include: 1. The LD failed to ensure quality control procedures and manufacturer's instructions were followed by TP. See D6014.
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently

	and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on record review, the manufacturer's instructions, and an interview with testing personnel (TP1); the laboratory director (LD) failed to ensure that laboratory personnel are performing the test methods as required for accurate and reliable results during the years of 2017 through 2019. Findings include: 1. The LD failed to ensure that TP1 read and understand the procedures manual, the laboratory's individual quality control plan (IQCP) and followed it. 2. The LD failed to ensure that TP1 read and understand the manufacturer's instructions and followed it.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on record review and an interview with testing personnel (TP2) and the laboratory director (LD); the LD failed to ensure prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. Findings: 1. The LD failed to ensure TP2 had the appropriate education for high complexity testing in the specialty of Histopathology. See D6171 and D6168.
D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: Based on record review, the Laboratory Personnel Report (CMS-209), and an interview with the staff manager, the laboratory failed to employ individuals who meet the qualification requirements of 493.1489. Finding: 1. The laboratory failed to ensure laboratory personnel meet the qualification requirements for performing highly complex testing in the specialty of Histopathology. See D6171.
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy,

or podiatry 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; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations.

This STANDARD is not met as evidenced by:
Based on review of the Laboratory Personnel Report (CMS-209), records, and an

	interview with the staff manager; the laboratory failed to ensure laboratory employees meet the qualification requirements for performing highly complex testing in the specialty of Histopathology. Findings: 1. The CMS 209 and personnel files were reviewed. 2. TP1 and TP2 are approved to perform tissue processing and testing in Histopathology. 3. Further, review showed TP2 failed to have any education credentials in their employee file. 4. On a recertification survey conducted on 05/03 /2019 at 2:30 PM, the staff manager confirmed the above findings.