Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D0984062	02/08/2022
Name of Provider or Supplier	**Street Address, City, State**	
Advanced Urology	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
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and interview; the laboratory failed to establish written policies and procedures for specimen submission, handling, and referral, prior to receiving patient specimens for COVID-19 antigen and SARS-CoV-2 Polymerase Chain Reaction (PCR) testing, affecting 11,594. Findings include: 1. The laboratory and SARS-CoV-2 PCR procedures manual, and quality control (QC) records were reviewed. 2. The QC records showed that the laboratory began performing COVID-19 antigen and SARS-CoV-2 PCR testing on May 15, 2021. 3. Review of the manuals revealed that the laboratory failed to include the following: *The step-by-step process to register patients for testing and what were their registration requirements; *When the patient elects to order PCR, what roles does each testing personnel (Antigen testers and PCR testers) perform in preparation of patient's sample; *Instructions for Specimen collection. *Step-by-Step instructions for Specimen labeling (accessioning), including patient name or unique patient identifier and, when appropriate, specimen source. *Specimen storage and preservation. *Conditions for specimen transportation. *Specimen acceptability and rejection. 4. The laboratory director (LD) documented on the CLIA application (CMS-116) that 11,594 COVID-19 Antigen and SARS-COV-2 PCR test have been performed during the period of January 2021 through January 2022. 5. On 03/02/2022 at 2:30 PM, the laboratory director and general supervisor confirmed the above findings.

D6101	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(11) The laboratory director must employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart. This STANDARD is not met as evidenced by: Based on record review, the Laboratory Personnel Report (CMS 209), and interview, the laboratory director (LD) failed to ensure the laboratory employed qualified personnel to accurately perform SARS-CoV-2 Polymerase Chain Reaction (PCR) tests and report test results prior to testing patients. Findings: 1. The employee files and CMS-209 were reviewed. 2. The LD failed to ensure five out of six testing personnel meet the education requirement for highly complex testing, prior to testing patients. See D6168, D6171. 3. On 03/02/2022 at 2:30 PM, the laboratory director confirmed the above findings.
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, CMS-209 (Laboratory Personnel Report), and interview; the laboratory failed to have individuals who meet the qualification requirements for performing high complexity of testing (D6171) for five out of six testing personnel (TP).
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 record review, lack of documentation, and interview, the laboratory failed to ensure laboratory employees meet the education qualification requirements for performing SARS-CoV-2 Polymerase Chain Reaction (PCR) testing prior to testing patients. Findings: 1. The employee files and the Laboratory Personnel Report (CMS-209) were reviewed. 2. The CMS 209 listed six testing personnel (TP1, TP2, TP3, TP4, TP5, and TP6) performing SARS-CoV-2 PCR testing in the laboratory. 3. The employee files revealed that TP1, TP2, TP3, TP4, TP5, and TP6 were trained, accessed for competency, and performing PCR testing. 4. Further review of these files showed the laboratory failed to have any documented proof of education for five out of six TP (TP1, TP2, TP3, TP4, and TP6). 5. On 03/02/2022 at 2:30 PM, the laboratory director confirmed the above findings.