

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 06D0684482	(X3) Date Survey Completed 12/16/2019
Name of Provider or Supplier Advanced Urology, Pllc	Street Address, City, State 1411 S Potomac St, Suite 210, Aurora, CO	
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
D6030	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12)</p> <p>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)(12) 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: Based on review of the Quality Assurance (QA) plan, personnel competency assessment records and staff interview, the laboratory director failed to ensure the established policy for competency assessment on individuals who conduct Urine Sediment Microscopic Examination was performed on four testing personnel in 2018. Findings Include: a. The QA plan states that competency will be performed twice in the first year of employment and annually thereafter and will be documented. b. Documentation of competency performance was observed from 2015 through 2017 and 2019, however no documentation existed that competency was performed in accordance with the established laboratory QA plan or Corrective Action plan for 2018. c. Staff confirmed that competency had been performed each year from 2015 through 2019 but documentation could not be found for 2018.</p>