

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0883791	(X3) Date Survey Completed 04/16/2018
Name of Provider or Supplier Advanced Urology Institute, Llc	Street Address, City, State 5747 38th Ave N, Saint Petersburg, FL	
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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES 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 competency record review and interview with the Medical Laboratory Technician (MLT), the laboratory failed to perform competency evaluations for urine microscopy for three (#10, #11, and #12) out of 12 Testing Personnel. Findings included: A review of the laboratory's CMS-209 Form titled Laboratory Personnel Report revealed Employees #10, #11, and #12 were testing personnel and medical doctors. During the competency record review it was discovered that Testing Personnel #10, #11, and #12 did not have competency records for performing urine microscopy. During an interview on 04/16/18 at 10:15 AM, the MLT confirmed that competency evaluations had not been performed on the three Testing Personnel (#10, #11, and #12).</p>
D5213	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1)</p> <p>The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program.</p> <p>This STANDARD is not met as evidenced by: Based on Split Sample Testing record review for two out of two years (2016-2018) and interview with Medical Laboratory Technician (MLT), the laboratory failed to</p>

allow all Testing Personnel to perform Split Sample Testing. Findings included: During record review of Split Sample Testing records for two out of two years (2016-2018) it was found that Testing Personnel names were not on the Split Sample Testing records for 03/16, 08/16, 02/17, 08/17 and 02/18. During interview on 04/16/18 at 10:30 AM, the MLT stated that the Split Sample Testing was only performed by the MLT.

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 observation, Quality Control record review, and interview with the Medical Laboratory Technician (MLT), the laboratory failed to perform quality control for urine microscopics for two out of two years (2016-2018). Findings included: An initial tour of the laboratory on 4/16/18 at approximately 9:40 a.m. revealed there were no pictographs to reference urine sedimentation. During Quality Control record review it was revealed there were no Urine Microscopic Quality Controls records. During an interview on 04/16/18 at 10:30 AM, the MLT stated that Quality Control was not performed for Urine Microscopics.