

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0298960	(X3) Date Survey Completed 02/19/2019
Name of Provider or Supplier Advanced Urology Institute	Street Address, City, State 210 S Lake St Ste 9, Leesburg, 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 record review and interview, the laboratory failed to establish a written policy to assess the training and competency of testing personnel. Findings: Review of the laboratory's procedure manual did not show a procedure on the assessment of employee training and competency. During an interview on 2/19/19 at 3:53 PM, the Technical Consultant acknowledged that they did not have a procedure for employee training and competency.</p>
D5400	<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 overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.</p> <p>This CONDITION is not met as evidenced by: Based on record review and interview, the laboratory's quality assessment program failed to monitor and evaluate the overall quality of the analytic system and correct identified problems. Cross Reference D5413. Based on observation, record review</p>

and interview, the laboratory failed to record the laboratory refrigerator temperature, and the temperature and humidity of the room where testing was performed from 7/1/18 to 2/19/19. Cross Reference D5433. Based on observation, interview and record review, the laboratory failed to follow its policy for calibrating two centrifuges from 7/1/18 to 2/19/19. Cross Reference D5451. Based on observation, record review and interview, the laboratory failed to perform quality controls at least once per day for patient urinalysis specimens tested from 7/1/18 to 2/19/19.

D5413

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(b)

The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:
Based on observation, record review and interview, the laboratory failed to record the laboratory refrigerator temperature, and the temperature and humidity of the room where testing was performed from 7/1/18 to 2/19/19. Findings: A tour of the laboratory at 1:20 PM revealed that there was no thermometer in the laboratory refrigerator or the laboratory, and no method to measure the humidity of the laboratory. Review of the laboratory's logs showed that the laboratory failed to record the refrigerator temperature, and the temperature and humidity of the room where testing was performed from 7/1/18 to 2/19/19. During an interview on 2/19/19 at 1:33 PM, the Technical Consultant acknowledged that there was no documentation showing that the laboratory refrigerator, and the temperature and humidity of the room where testing was performed was recorded.

D5433

MAINTENANCE AND FUNCTION CHECKS
CFR(s): 493.1254(b)(1)

For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.

This STANDARD is not met as evidenced by:
Based on observation, interview and record review, the laboratory failed to follow its policy for calibrating two centrifuges from 7/1/18 to 2/19/19. Findings: The laboratory was using the procedure titled, "Physician Performed Microscopy Quality Assurance Manual" as part of their Certificate of Compliance laboratory's procedure manual. Under the topic of procedures in the section on centrifuges it showed, "Calibrate centrifuge quarterly at each speed required for testing." Observation of the two centrifuges in the laboratory showed that the service sticker on each centrifuge was

	<p>dated 7/31/07. No other documentation of preventative maintenance or calibration was available. During an interview on 2/19/19 at 2:42 PM, the Technical Consultant acknowledged that there was no other documentation of preventative maintenance or calibration of the centrifuges.</p>
<p>D5451</p>	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(iii)(g)</p> <p>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-- At least once a day patient specimens are assayed or examined perform the following for-- Test procedures producing graded or titered results include a negative control material and a control material with graded or titered reactivity, respectively; 493.1256 (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on observation, record review and interview, the laboratory failed to perform quality controls at least once a day patient specimens for urinalysis are tested form 7/1 /18 to 2/19/19. Findings: The laboratory performs urinalysis using Chemstrip 10 MD Reagent Strips and Medline Urinalysis Reagent Strips. A tour of the laboratory revealed that there were no quality control reagents for the urine dipstick testing performed in the laboratory. Review of the laboratory's logs showed that there was no quality control results recorded. During an interview on 2/19/19 at 1:25 PM, the Technical Consultant acknowledged that the laboratory was not running controls for urinalysis testing.</p>
<p>D5805</p>	<p>TEST REPORT CFR(s): 493.1291(c)</p> <p>The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory test reports did not identify the name and location where the laboratory testing was performed for 2 out of 2 patients from 7/1/18 to 2/19/19 Findings: A review of patient test reports from 7/1/18 to 2/19 /19 was performed. The patient test reports for patient #1 (4/10/18) and patient #2 (2 /19/19) failed to list the name and location of where the the laboratory testing was performed. During an interview on 2/19/19 at 4:21 PM, the Technical Consultant acknowledged that the name and location where the laboratory testing was performed was not listed on the reports.</p>
<p>D6000</p>	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p>

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 and interview, the Laboratory Director failed to provide overall management and direction. Cross Reference D6007. Based on observation, interview and record review, the Laboratory Director failed to ensure that testing systems used in the laboratory provided quality laboratory services for all aspects of testing performance, including preanalytic, analytic and postanalytical phases of testing from 7/1/18 to 2/19/19.

D6007

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(1)

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)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing;

This STANDARD is not met as evidenced by:

Based on observation, interview, and record review, the Laboratory Director failed to ensure that testing systems used in the laboratory provided quality laboratory services for all aspects of testing performance, including preanalytic, analytic and postanalytical phases of testing from 7/1/18 to 2/19/19. Preanalytic: Based on record review and interview, the Laboratory Director failed to identify that the laboratory did not establish a written policy to assess the training and competency of testing personnel. Findings: Review of the laboratory's procedure manual did not show a procedure on the assessment of employee training and competency. During an interview on 2/19/19 at 3:53 PM, the Technical Consultant acknowledged that they did not have a procedure on employee training and competency. Analytic: 1. Based on observation, record review and interview, the Laboratory Director failed to identify that the laboratory did not record the laboratory refrigerator temperature, and the temperature and humidity of the room where testing was performed from 7/1/18 to 2/19/19. Findings: A tour of the laboratory at 1:20 PM revealed that there was no thermometer in the laboratory refrigerator or the laboratory, and no method to measure the humidity of the laboratory. 2. Based on observation, interview and record review, the Laboratory Director failed to identify that the laboratory did not follow its policy for calibrating two centrifuges from 7/1/18 to 2/19/19. Findings: The laboratory was using the procedure titled, "Physician Performed Microscopy Quality Assurance Manual" as part of their Certificate of Compliance laboratory's procedure manual. Under the topic of procedures in the section on centrifuges it read, "Calibrate centrifuge quarterly at each speed required for testing." Observation of the two centrifuges in the laboratory showed that the service sticker on each centrifuge was dated 7/31/07. No other documentation of preventative maintenance or calibration was available. During an interview on 2/19/19 at 2:42 PM, the Technical Consultant acknowledged that there was no other documentation of preventative maintenance or

calibration on the centrifuges. 3. Based on record review and interview, the Laboratory Director failed to identify the laboratory's failure to perform quality controls at least once a day patient specimens for urinalysis are tested from 7/1/18 to 2/19/19. Findings: The laboratory performs urinalysis using Chemstrip 10 MD Reagent Strips and Medline Urinalysis Reagent Strips. A tour of the laboratory revealed that there were no quality control reagents for the urine dipstick testing performed in the laboratory. Review of laboratory's logs showed that there was no quality control results recorded. During an interview on 2/19/19 at 1:25 PM, the Technical Consultant acknowledged that the laboratory was not running controls for urinalysis testing.

Postanalytic: Based on record review and interview, the Laboratory Director failed to identify that the laboratory test reports did not identify the name and location where the laboratory testing was performed for 2 out of 2 patients from 7/1/18 to 2/19/19 Findings: A review of patient test reports from 7/1/18 to 2/19/19 was performed. The patient test reports for patient #1 (4/10/18) and patient #2 (2/19/19) failed to list the name and location of where the the laboratory testing was performed. During an interview on 2/19/19 at 4:21 PM, the Technical Consultant acknowledged that the name and location where the laboratory testing was performed was not listed on the reports.