Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	06D0513593	04/11/2018
Name of Provider or Supplier	**Street Address, City, State**	
Adventhealth Urology At Denver	850 E Harvard Ave, Suite 305, Denver, 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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 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. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies, personnel competency records, and staff interview, the laboratory failed to follow their policy to document all required components of competency when 3 of 3 testing personnel were assessed for the prothrombin time (PT) test and the automated semen analysis test in 2017. Findings include: a. The laboratory's policy for personnel competency states, "The procedures for evaluation of the competency of the staff must include, but are not limited to: direct observation of routine patient test performance, monitoring the recording and reporting of test results, review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records, direct observation of performance of instrument maintenance and function checks, assessment of test performance through testing internal and/or external proficiency testing samples, and assessment of problem solving skills." b. Records showed the competency assessments in 2017 of 3 of 3 testing personnel who perform prothrombin time testing on the Abbott i-STAT involved a written quiz, reading the test procedure, and an attestation, signed by the testing personnel and the technical consultant, stating, "I am able to demonstrate and understand 1) patient specimen collection, handling and identification, 2) testing procedure, 3) quality control, 4) reagent test pack and control handing and storage requirements, 5) documentation and result reporting procedures, and 5) (sic) trouble shooting error messages for the i-STAT system. c. Records showed the competency assessments in 2017 of 3 of 3 testing personnel who perform automated semen analysis using the SQA-V Gold Semen Analyzer involved a written quiz, reading the test procedure, viewing SQA-V videos,

	and an attestation, signed by the testing personnel and the technical consultant, stating, "I have read the SQA-V Analyzer procedure and viewed the MES-Global videos. I can perform daily and weekly maintenance procedures. I understand the importance of a properly filled capillary in order to obtain accurate results. I understand all reagent storage requirements and proper handling and use. I have performed Quality Control testing and understand how to troubleshoot and document failed QC testing. I can accurately perform patient testing along with documentation of results into the patient's EMR." d. Staff confirmed the evaluations did not contain all the components of competency assessment as required by federal CLIA regulation.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies, the lack of verification records, and staff interview, the laboratory failed in 2018 to verify before initial patient use on January 26, 2018, the manufacturer's stated performance specifications of the prothrombin time (PT) test using a replacement Abbott i-STAT portable clinical analyzer (serial #312253). Findings include: a. On 1-26-18, the laboratory began using a replacement i-STAT analyzer for PT testing of patient specimens. b. The laboratory's policy states, "Method performance will be verified (validated) by testing 1) accuracy, 2) precision, 3) reportable range of test results for the test system, and 4) verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. Documentation will be maintained for 2 years after test instrument and/or method is discontinued. TUCC will ensure that the test systems, equipment, instruments, reagents, materials and supplies function according to manufacturer's specification." c. No documentation existed that the laboratory verified that they could obtain on the replacement i-STAT analyzer, the analytical claims of the manufacturer. d. Staff stated they were unaware of this regulatory requirement for replacement analyzers and confirmed that the manufacturer's performance specifications had not been verified using this replacement test system before reporting patient results.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the

	laboratory's patient population. This STANDARD is not met as evidenced by: Based on a review of the operator's manual, laboratory policy, maintenance records, and staff interview, the laboratory failed in 2018 to take corrective actions on 65 of 65 days of testing from January through March when the ambient humidity within the laboratory was outside of the acceptable range for the Beckman Coulter Access 2 Immunoassay Analyzer. Findings include: a. The Beckman Coulter operator's manual stated the humidity in the laboratory for testing must be between 20-80% relative humidity (RH). b. The laboratory's policy stated, " If the humidity exceeds the manufacturer's limits, patient testing should not continue until this problem is corrected. Notify the Clinical/ancillary services manager of the problem so corrective measures may be taken. Document actions taken on the Laboratory Temperature and Humidity Form and fill out a Variance Report for documentation." c. Staff stated they were aware the humidity level in the laboratory had been outside of the acceptable range for the immunoassay analyzer, but they took no corrective action. d. Staff confirmed they had been testing patient specimens when the ambient humidity of the laboratory was outside of the manufacturer's acceptable range, and they had taken no corrective action as required by the federal CLIA regulation.
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 the lack of training records and staff confirmation, the laboratory failed to ensure that 1 of 3 new testing personnel met the qualification requirements to perform high complexity gross description of tissue testing (Ref 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 a review of personnel records and staff confirmation, the laboratory failed to ensure that 1 of 3 new testing personnel, hired 3-19-18, was qualified to perform the high complexity test of gross description of tissues. The laboratory provided a high school diploma that had been earned in 1994, but no documentation was provided to show that the individual had attended a medical laboratory or clinical laboratory training program approved by HHS, or had attended an official U.S. military medical laboratory procedures training course, or had received training in performing the gross description of tissues before September 1, 1997 as required by federal CLIA regulation.