

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D0934367	(X3) Date Survey Completed 10/05/2018
Name of Provider or Supplier Ecu Health Urology - Greenville	Street Address, City, State 275 Bethesda Drive, Greenville, NC	
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 review of personnel records, review of laboratory's policies and procedures, and interview with testing personnel (TP) 10/05/18, the laboratory failed to establish competency procedures that meet the regulations as stated in section 493.1413 (b)(8) of the 42 CFR Part 493 Requirements for Laboratories. Section 493.1413 (b)(8) states: "The procedures for evaluation of the competency of the staff (testing personnel) must include, but are not limited to.... Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing; 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 previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and Assessment of problem solving skills; Review of laboratory policies and procedures revealed policy "PSA TESTING PERSONNEL TRAINING...When a new employee is trained...a complete checklist is covered by Lab Director....with new employee. When they are felt to be adequately trained, they are signed off on the checklist by Lab Director. (Checklist Provided)....Employees are then re-evaluated at 6 months from initial training. After completing initial training and 6 month review, employees are evaluated yearly." The policy does not indicate how the evaluations are conducted and documented, and does not include the criteria used for the evaluation. Review of personnel records revealed testing personnel competency evaluations were documented on the laboratory's "AIA-360 TRAINING</p>

CHECKLIST", the checklist fails to indicate it is a competency evaluation and fails to include the required procedures for evaluation of the competency of the testing personnel as required in section 493.1413 (b)(8) of the 42 CFR Part 493 Requirements for Laboratories. Interview with TP # 8 at time of survey confirmed the laboratory did not have an established testing personnel competency policy and that testing personnel competency evaluations failed to include the required procedures for evaluation of testing personnel competency.