

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 42D2038406	(X3) Date Survey Completed 06/26/2018
Name of Provider or Supplier Doctors Care - Red Bank	Street Address, City, State 1847 S Lake Drive, Lexington, SC	
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
D5211	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: During an onsite recertification survey on 06/26/2018, based on proficiency testing record review, and testing personnel interview, the laboratory failed to review and evaluate proficiency testing results for 1 of 7 proficiency testing events reviewed from 2016 through 2018 (2017, Event 2). Findings include: 1. Review of proficiency testing results revealed the following scores: a. 2017, Event 2; 50% for urine sediment identification There was no documentation of director review and evaluation or corrective action for the failure. 2. Testing personnel confirmed during onsite interview on 06/26/2018 at 03:30pm, that the laboratory had failed to review and evaluate proficiency testing results.</p>
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by:</p>

During an onsite recertification survey on 06/26/2018, based on laboratory procedure manual review, laboratory room temperature record review, and staff interview, it was determined that the laboratory failed to document acceptable room temperatures between August 18, 2017 through December 24, 2017. Findings include: 1. The laboratory procedure manual had a required room temperature range between 64 and 90 degrees Celsius. 2. Review of the laboratory's temperature records revealed that room temperatures were not recorded for a total of 14 days between August 18, 2017 through December 24, 2017. There was no corrective action for the missing temperatures during this time period available for review. 3. Testing personnel confirmed during an onsite interview at 3:30 pm that the laboratory had failed to document proper room temperatures.