

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 42D2086236	(X3) Date Survey Completed 02/28/2018
Name of Provider or Supplier Emergency Md	Street Address, City, State 2498 N Pleasantburg Dr, Greenville, 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
D5809	<p>TEST REPORT CFR(s): 493.1291(e)</p> <p>The laboratory must, upon request, make available to clients a list of test methods employed by the laboratory and, as applicable, the performance specifications established or verified as specified in 493.1253. In addition, information that may affect the interpretation of test results, for example test interferences, must be provided upon request. Pertinent updates on testing information must be provided to clients whenever changes occur that affect the test results or interpretation of test results.</p> <p>This STANDARD is not met as evidenced by: During an onsite recertification survey on 2/28/2018, based on the NanoEntek FRENED Prostate Specific Antigen (PSA) Plus package insert review and patient record review, the laboratory failed to include on the PSA test report the method of testing used as information that may affect the interpretation of test results for 3 random patient charts reviewed from 2017 and 2018. Findings include: 1. The laboratory started testing on the NanoEntek FRENED analyzer in June 2016. 2. The Nanoentek FRENED PSA Plus test manufacturer's package insert stated that results reported must include the identity of the assay used, as PSA testing values vary among methods and cannot be used interchangeably to monitor PSA levels. 3. Random review of patients' charts revealed that the PSA assay used was not included on the following reports: a. Patient 14309, reported 12/29/2017 b. Patient 15365, reported 2/2/2018 c. Patient 15895, reported 2/16/2018 4. The laboratory failed to include the identity of the PSA method used on the test report, as required.</p>