

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 42D0877753	(X3) Date Survey Completed 09/11/2019
Name of Provider or Supplier Upstate Public Health Region	Street Address, City, State 220 Mcgee Road, Anderson, 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
D5775	<p>COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c)</p> <p>(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.</p> <p>This STANDARD is not met as evidenced by: Based on laboratory procedure manual review, lack of documentation and testing personnel interview, the laboratory failed to document twice a year comparison for the Potassium Hydroxide (KOH) wet prep test for one of three years reviewed from 2017 to 2019(2017). Findings include: 1. The laboratory procedure manual review on 09/11/2019 stated that the KOH wet prep test was performed at multiple locations and that the accuracy of the test must be verified at least two times annually. 2. Documentation review on 09/11/2019 revealed that a twice a year KOH test comparison was unavailable for review for the year 2017. 3. Testing personnel confirmed during the onsite exit interview on 09/11/2019 at 3:00 pm that the comparisons had not been performed in 2017.</p>
D6054	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)</p> <p>The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on the CMS 209 review, lack of documentation and testing personnel interview, the laboratory failed to ensure that testing personnel were evaluated annually after the first year of testing patient specimens for 1 of 8 testing personnel (employees 1 through 8 on CMS 209) for 2 of 2 years reviewed (2017 and 2018) . Findings include: 1. The laboratory listed 9 testing personnel on the CMS-209 on the day of the survey. 2. Documentation review on 09/11/19 revealed that an annual training and evaluation was unavailable for review on the day of the survey for 1 of 8 testing personnel (employees 6 on CMS 209) for two of two years reviewed (2017 and 2018) . 3. Testing personnel confirmed during an onsite interview on 09/11/19 at 3:00pm that the laboratory had failed to ensure that testing personnel were evaluated at least annually after the first year of testing patient specimens.