

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2030207	(X3) Date Survey Completed 03/29/2019
Name of Provider or Supplier Andrew Chung Md, Pllc	Street Address, City, State 3600 Gaston Ave #755, Dallas, TX	
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
D0000	D000The following deficiencies are a result of a desk review of proficiency testing scores obtained from the CMS (Center for Medicare Services) national database and verified with the proficiency testing company, American Proficiency Institute (API). The facility was found to be out of compliance with the conditions of participation of the CLIA program. The following CONDITION LEVEL DEFICIENCIES were found to be out of compliance: 493.803 successful participation in a proficiency testing program 493.1403 laboratories performing moderate complexity testing; laboratory director
D2087	<p>ROUTINE CHEMISTRY CFR(s): 493.841(a)</p> <p>Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on a proficiency testing desk review of CMS form 155 and American proficiency Institute API records found that the laboratory failed to attain a satisfactory score of at least 80% of acceptable responses for each analyte in the subspecialty of chemistry for the analytes Total Bilirubin and Triglycerides. Findings: 1. API 2018 - 3rd event the laboratory received the unsatisfactory score of 20% for Total Bilirubin. 2. API 2018 - 3rd event the laboratory received the unsatisfactory score of 60% for Triglycerides.</p>
D2088	<p>ROUTINE CHEMISTRY CFR(s): 493.841(b)</p> <p>Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.</p>

	<p>This STANDARD is not met as evidenced by: Review of the CMS report 155 and API proficiency testing records found that the laboratory failed to achieve a satisfactory score of at least 80% for the overall chemistry testing event score. Findings: 1. API 2019 - 1st event reported an event chemistry score of 0%.</p>
<p>D2089</p>	<p>ROUTINE CHEMISTRY CFR(s): 493.841(c)</p> <p>Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3)The laboratory participated in the previous two proficiency testing events.</p> <p>This STANDARD is not met as evidenced by: Review of the CMS report 155 and API proficiency testing records found that the laboratory failed to participate in the 2019 1st Testing Event resulting in a score of 0% for the all analytes in the speciality of Chemistry, constituting unsatisfactory performance. Findings: 1. API 2019 - 1st event reported No Data Received resulting in the following unsatisfactory scores: Routine Chemistry event 0% Alanine aminotransferase ALT 0% Albumin 0% Alkaline Phosphatase 0% Aspartate aminotransferase AST 0% Bilirubin Total 0% Calcium 0% Total Cholesterol 0% Cholesterol HDL 0% Creatinine 0% Glucose 0% Potassium 0% Sodium 0% Total Protein 0% Triglycerides 0% Blood Urea Nitrogen BUN 0%</p>
<p>D2096</p>	<p>ROUTINE CHEMISTRY CFR(s): 493.841(f)</p> <p>Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.</p> <p>This STANDARD is not met as evidenced by: Based on desk review of proficiency testing records, it was determined the laboratory failed to achieve satisfactory performance (80% or greater) for the same analyte in two consecutive testing events or two out of three consecutive testing events in the specialty of Chemistry for the analytes Total Bilirubin and Triglycerides. Two out of three unsatisfactory scores results in unsuccessful PT performance. Findings include: 1. API 2018 - 3rd testing event the laboratory received the following unsatisfactory scores: Total Bilirubin 20% Triglycerides 60% 2. API 2019 - 1st testing event the laboratory received the following unsatisfactory scores: Total Bilirubin 0% Triglycerides 0%</p>
<p>D2099</p>	<p>ENDOCRINOLOGY CFR(s): 493.843(b)</p>

	<p>Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.</p> <p>This STANDARD is not met as evidenced by: Based on review of CMS form 155 and American Proficiency Institute API records the laboratory failed to obtain at least an 80 percent overall sub-specialty score for Endocrinology. Findings: 1. API 2019 - 1st testing event score was 0%.</p>
D2100	<p>ENDOCRINOLOGY CFR(s): 493.843(c)</p> <p>Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events.</p> <p>This STANDARD is not met as evidenced by: Review of the CMS report 155 and proficiency testing records found that the laboratory failed to participate in the 2019 1st Testing Event for Endocrinology, resulting in a score of 0% for all regulated analytes for the speciality of Endocrinology, constituting unsatisfactory performance. Findings: 1. Laboratory received the following unsatisfactory scores from API 2019-1st event: Cortisol 0% Free Thyroxine 0% Thyroid Stimulating Hormone TSH - 0%</p>
D6000	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on a desk review of laboratory proficiency testing performance it was revealed that the laboratory director failed to provide overall management and direction of the laboratory services. Refer to D6016</p>
D6016	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as</p>

required under Subpart H of this part;

This STANDARD is not met as evidenced by:

Based on a desk review of proficiency testing results it was revealed that the laboratory director failed to ensure the overall quality of the laboratory services provided. The laboratory director failed to ensure successful participation in a HHS approved proficiency testing program. Refer to D2096