

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0714948	(X3) Date Survey Completed 04/17/2019
Name of Provider or Supplier Brian D Ardel Md Pa	Street Address, City, State 3417-D Tamiami Tr, Port Charlotte, FL	
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
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: Based on record review and interview with laboratory personnel, the laboratory failed to get at least 80 percent for one analyte for the first testing event of 2017 and one analyte in the first testing event of 2018. Findings include: Review of American Proficiency Institute (API) proficiency testing records for 2017 through the present on 04/17/2019 revealed that the laboratory received a 60% for iron (Fe) for the first event of 2017, and a 60% for alanine transaminase (ALT) for the first testing event of 2018. During an interview with testing person A at 10:40 a.m. on 04/17/2019, she confirmed that they had received unsatisfactory results in these analytes.</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: Based on record review and interview with laboratory personnel, there was no documentation to indicate that annual competency evaluations were done in 2018 for two of two moderate complexity personnel. Findings include: Review of personnel competency and training records on 04/17/2019 revealed that there was no competency evaluation for either of the two testing personnel for 2018. During an</p>

interview with testing person A. at 11:15 a.m. on 04/17/19, she confirmed that there were no competency evaluations in the personnel binder for either of two testing personnel for 2018.