

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2005875	(X3) Date Survey Completed 10/30/2019
Name of Provider or Supplier Joselito C Cabaccan, Md	Street Address, City, State 2690 S White Rd, Ste 50, San Jose, CA	
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
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: Based on review of 2019 College of American Pathologists (CAP) proficiency testing (PT) records review and laboratory staff interviews on 10/30/19, the laboratory failed to maintain copies of the PT program's attestation statements signed by the laboratory director to document that PT samples were tested in the same manner as patient specimens. The findings included: a. The laboratory failed to maintain copies of the following PT program's attestation statements signed by the laboratory director: Module Description PT Event TM Tumor markers 1, 2 VITD 25-OH Vitamin D, Total 1 ING Insulin, Gastrin, C-Peptide, PTH 1, 2 b. The laboratory staff confirmed by interview on 10/30/19 at 11.01 a.m. that the PT attestation statements were not signed by the laboratory director. c. The laboratory reported performing approximately 18,300 endocrinology patient tests annually.</p>