

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2030919	(X3) Date Survey Completed 03/19/2018
Name of Provider or Supplier Raymond I. Press Md	Street Address, City, State 3965 Fifth Ave Ste 430, San Diego, 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
D2075	<p>GENERAL IMMUNOLOGY CFR(s): 493.837(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 reviews of 2017: 1st event proficiency testing reports from CMS (report 155D, Individual laboratory profile) and API (American Proficiency Institute), laboratory proficiency testing records, and patients test reports; and interview with laboratory personnel, the laboratory failed to attain a score of at least 80% for RF IgM (Rheumatoid Factor) using the TheraTest EIA system, constituting unsatisfactory analyte performance. Findings include: a. CMS and API reported the score of 0% for RF. b. Laboratory proficiency testing records revealed the laboratory reported 5 unacceptable results out of 5 for RF IgM. c. Laboratory personnel affirmed (3/19/18) the aforementioned unacceptable results and unsatisfactory score of 0%. d. The reliability and quality of results reported for RF IgM could not be assured. Based on the stated estimated annual test volume, the laboratory reported approximately 18 RF IgM results each month. A few examples during the timeframe January to April 2017 are as follows: Date Sample ID ----- 1/22/17 11225406 2/18/17 12094808 3/25/17 2162904 4/09/17 2215363 .</p>
D2076	<p>GENERAL IMMUNOLOGY CFR(s): 493.837(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:</p>

Based on reviews of 2017: 1st event proficiency testing reports from CMS (report 155D, Individual laboratory profile) and API (American Proficiency Institute), laboratory proficiency testing records, and patients test reports; and interview with laboratory personnel, the laboratory failed to attain an overall testing event score of at least 80%, constituting unsatisfactory performance in Immunology. Findings include:

- a. CMS reported the overall Immunology score of 40% for 2017: event 1.
- b. API reported individual analytes scores as follows: ANA80% RF, IgM0%
- c. Laboratory personnel affirmed (3/19/18) the aforementioned scores; and thus, the overall Immunology score of 40%.
- d. See D2075 .