

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D0685825	<b>(X3) Date Survey Completed</b>  02/20/2019
<b>Name of Provider or Supplier</b>  Julio J Valdes Md Pa	<b>Street Address, City, State</b>  4506 N Armenia Ave, Tampa, FL	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2016</b>	<p><b>SUCCESSFUL PARTICIPATION</b> CFR(s): 493.803(a)(b)(c)</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.</p> <p>This CONDITION is not met as evidenced by: Based on review of American Proficiency Institute (API) proficiency testing and American Association of Bioanalysts (AAB) proficiency testing results and interview with the Technical Consultant, the laboratory had unsuccessful performance for Erythrocytes and Leukocytes for 2 out of 4 (2nd and 3rd testing event in 2017 and 2nd and 3rd testing events in 2018) testing events reviewed (See D2130).</p>
<b>D2130</b>	<p><b>HEMATOLOGY</b> CFR(s): 493.851(f)</p>

Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:

Based on review of American Proficiency Institute (API) proficiency and American Association of Bioanalysts (AAB) proficiency testing results and interview with the Technical Consultant, the laboratory had 2 out of 3 unsuccessful testing events for Erythrocytes and Leukocytes in the specialty of Hematology. Findings Included: Review of 2017 API and 2018 AAB proficiency testing results found the AAB 2018 1st Event had a 0% for Erythrocytes and Leukocytes and the AAB 2018 3rd testing event had a 0% for Erythrocytes and Leukocytes. Interview on 02/20/2019 at 12:30 PM Technical Consultant stated the lab was late enrolling for API proficiency testing so the laboratory received 0% for all analytes for the Hematology 2018 1st Event. The Technical Consultant stated that Testing Personnel #C did not know the laboratory tested for erythrocytes and leukocytes so the laboratory received 0% for AAB Hematology 2018 3rd Event for Erythrocytes and Leukocytes.

**D6015**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(4)

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) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed.

This STANDARD is not met as evidenced by:

Based on American Proficiency Institute (API) and American Association of Bioanalysts (AAB) proficiency testing record review and interview with the Technical Consultant, the Laboratory Director failed to ensure the laboratory was enrolled for Hematology proficiency testing for 2018. Findings Included: Review of API proficiency testing results revealed that the laboratory was enrolled in proficiency testing in 2017 for Hematology. Review of AAB proficiency revealed Hematology proficiency testing records for the 2nd and 3rd Event for 2018. Interview on 02/20/2019 at 12:30 PM the Technical Consultant stated the laboratory missed the enrollment time for 2018 API Hematology proficiency testing so the laboratory enrolled with 2018 AAB Hematology proficiency testing.