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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 40D1012245 | (X3) Date Survey Completed 02/14/2018 |
| Name of Provider or Supplier Laboratorio Clinico San Vicente | Street Address, City, State Calle Tulio Otero #15, Vega Baja, PR | |
| 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 |
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| D2127 | <p>HEMATOLOGY CFR(s): 493.851(d)</p> <p>Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on Puerto Rico Proficiency Testing Program records reviewed (2016-2017) and laboratory director interview on February 14, 2018 at 10:00 A.M., it was determined that the laboratory failed to report the hematology proficiency testing results within the time frame established by the program. The findings include: 1. Proficiency testing records were reviewed from February 2016 to July 2017. 2. The deadline of the first testing event report of hematology tests was April 1, 2016. 3. The laboratory did not report the first testing event of hematology within the time frame established by the Proficiency Testing Program and results in a score of 0 for the testing event. 4. The laboratory director confirmed on February 14, 2018 at 10:00 A. M. that the laboratory did not report the hematology proficiency testing results of the first testing event within the time frame established by the Proficiency Testing Program.</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 required under Subpart H of this part;</p> |

This STANDARD is not met as evidenced by:
Based on Puerto Rico Proficiency testing records review and laboratory director interview on February 14, 2018 at 10:00 AM, it was determined that the laboratory failed to ensure that proficiency testing samples were tested as required under Subpart H requirements. Refer to D2127.