

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0705731	(X3) Date Survey Completed 12/04/2018
Name of Provider or Supplier Laboratorio Clinico Santana	Street Address, City, State Calle 25 De Julio #45, Guanica, 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
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on Puerto Rico Proficiency testing records review (2017-2018) and laboratory director interview on December 4, 2018 at 9:45 A.M., it was determined that the laboratory director and testing personnel failed to sign the attestation statements. The findings include: 1. Puerto Rico Proficiency testing records were review from February 2017 to November 2018. 2. The laboratory director and testing personnel did not sign the attestation statements of the Proficiency testing records since February 2017. 3. The laboratory general supervisor confirmed on December 4, 2018 at 9:45 A. M that the laboratory director and testing personnel failed to sign the attestation statements since 2017.</p>
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</p>

the PT event.

This STANDARD is not met as evidenced by:

1. Based on Puerto Rico Proficiency testing records review from February 2016 to November 2018 and laboratory director interview on December 4, 2018 at 9:20 AM, it was determined that the laboratory failed to maintain the proficiency testing event records. The findings include: a. Review of Puerto Rico proficiency testing records from February 2016 to November 2018, showed that the laboratory did not maintain the following proficiency testing event results: March 2017, April 2017, June 2017 and July 2017. b. The laboratory director confirmed on December 4, 2018 at 9:20 A.M., that the laboratory did not maintain these proficiency testing event results. 2. Based on American Association of Bioanalysts (AAB) Laboratory Proficiency testing records review from February 2017 to October 2018 and laboratory director interview on December 4, 2018 at 9:30 AM, it was determined that the laboratory failed to maintain the proficiency testing event records. The findings include: a. Review of AAB proficiency testing records from February 2018 to November 2018, showed that the laboratory did not maintain the proficiency testing records from year 2017. b. The laboratory director confirmed on December 4, 2018 at 9:20 A.M., that the laboratory did not maintain these proficiency testing event records.

D3037

RETENTION REQUIREMENTS

CFR(s): 493.1105(a)(4)

Proficiency testing records. Retain all proficiency testing records for at least 2 years.

This STANDARD is not met as evidenced by:

Based on review of Puerto Rico Proficiency Testing records (2017-2018) and laboratory director interview on December 4, 2018 at 9:45 AM, it was determined that the laboratory failed to retain proficiency testing records for at least 2 years. The findings include: 1. Puerto Rico Proficiency Testing records were reviewed from February 2017 to November 2018. 2. The laboratory did not have available the proficiency testing results from March 2017 to July 2017. 3. The laboratory director confirmed on December 4, 2018 at 9:45 A.M. , that the laboratory did not have available the Proficiency Testing results from these months.

D5437

CALIBRATION AND CALIBRATION VERIFICATION

CFR(s): 493.1255(a)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b) (3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.

This STANDARD is not met as evidenced by:

Based on hematology calibration verification records review, manufacturer's instructions and laboratory director interview on December 4, 2018 at 11:20 A.M., it was determined that the laboratory failed to perform the calibration verification procedures with at least the frequency recommended by the manufacturer (each six months) for the hematology tests performed by the Cell Dyn 1600 system. The findings include: 1. The laboratory uses a Cell Dyn 1600 hematology system for CBC (Complete blood count) patient's tests. 2. The manufacturer's instructions establishes that for the Cell Dyn 1600 system, the calibration verification procedures must be performed each six months. 3. From 2017 to 2018, the calibration verification records showed that the laboratory did not perform at least every 6 months the calibration verification procedures for the Cell Dyn 1600 hematology system. In year 2018 the calibration verification for Cell Dyn 1600 system was performed on October 2018. 4. The laboratory director confirmed on December 4, 2018 at 11:20 A.M., that the laboratory did not perform at least 6 months the calibration verification procedures for Cell Dyn 1600 system.

D5439

CALIBRATION AND CALIBRATION VERIFICATION
CFR(s): 493.1255(b)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:
Based on lack of routine chemistry calibration verification records (year 2017 to 2018) and interview with the laboratory director on December 4, 2018 11:00 AM, it was determined that the laboratory did not perform , at least every 6 months, the calibration verification procedures for the routine chemistry tests processed by the Envoy 500 system. The findings include: 1. The laboratory used the Envoy 500 system to perform routine chemistry tests. 2. Review of routine chemistry calibration verification records from January 2017 to December 2018, showed that the laboratory did not perform the calibration verification procedures for routine chemistry tests since January 2017. 3. The laboratory director confirmed on December 4, 2018 at 11:00 A.M. that the laboratory did not perform at least six months the calibration verification procedures for routine chemistry tests performed by the Envoy 500 system. 4. The laboratory processed 34,074 routine chemistry patient's tests from year 2017.

D6089

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(4)(i)

The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part.

This STANDARD is not met as evidenced by:

Based on Puerto Rico Proficiency Program testing records review (2017 to 2018) and laboratory director interview on December 4, 2018 at 11:45 AM, it was determined that the laboratory director failed to ensure that proficiency testing samples were tested as required under Subpart H requirements. Refer to D2009 and D2015.

D6102

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(12)

The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:

Based on testing personnel records review and laboratory director technical interview on December 4, 2018 at 10:00 A.M., it was found that the laboratory director did not make sure that the new testing personnel received the appropriate training before beginning to perform patient tests. The findings include: 1. The testing personnel was hired and performed patient testing since December 2017. 2. The laboratory did not have any document related to testing personnel training. 3. The laboratory director confirmed on December 4, 2018 at 10:00 A.M., that the laboratory did not document the testing personnel training prior to perform patient tests.

D6103

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(13)

The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills.

This STANDARD is not met as evidenced by:

Based on personnel records review and laboratory director interview at 10:30 A.M. on December 4, 2018, it was determined that the laboratory director failed to provide bi-annually the competence evaluation to the testing personnel that performed the high and moderate complexity tests. The findings include: 1. The technical supervisor failed to perform the bi annual competency evaluation to the testing personnel (MT # 7037) that include at least the following requirements since December 2017: a. Direct observations of routine patient test performance, including patient preparation, if

applicable, specimen handling, processing and testing. b. Monitoring, recording and reporting of test results. c. Review of intermediate test results or worksheets, quality control records, proficiency testing results and preventive maintenance records. d. Direct observation of performance of instrument maintenance and function checks. e. Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples.