

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0912847	(X3) Date Survey Completed 11/04/2020
Name of Provider or Supplier Laboratorio Clinico Villa Ana Aguas Buenas Iii	Street Address, City, State Carr 174 Km 21 , Hm 7, Aguas Buenas, 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
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 Puerto Rico Proficiency Testing Program (PRPTP) records review from February 2019 to November 2020 and laboratory testing personnel interview on November 5, 2020 at 9:38 AM, it was determined that the laboratory failed to maintain the proficiency testing event records. The findings include: 1. Review of proficiency testing records from February 2019 to November 2020, showed that the laboratory did not maintain the following proficiency testing event records: October 2019 and November 2019. 2. The laboratory testing personnel confirmed on November 5, 2020, that the laboratory did not maintain these proficiency testing event records.</p>
D2128	<p>HEMATOLOGY CFR(s): 493.851(e)</p> <p>(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training</p>

and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

This STANDARD is not met as evidenced by:

Based on Puerto Rico Proficiency Testing Program (PRPTP) records review from February 2019 to November 2020 and laboratory testing personnel interview on November 5, 2020 at 9:40 AM, it was determined that the laboratory failed to take and document corrective actions when it obtained an unsatisfactory results in hematology specialties. The findings include: 1. Puerto Rico Proficiency Testing Program (PRPTP) records and results were reviewed from February 2019 to November 2020. 2. Review of Proficiency Testing records showed that the laboratory obtained unsatisfactory results of 84 percent in Differential White Blood Cell for 5 parameter instrument on July 2020 (PRPTP second testing event). No remedial actions were taken. 3. The testing personnel confirmed on November 5, 2020, that the laboratory did not take corrective actions on July 2020 testing event.

D5209

PERSONNEL COMPETENCY ASSESSMENT POLICIES
CFR(s): 493.1235

As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.

This STANDARD is not met as evidenced by:

Based on personnel records review from January 2019 to November 5, 2020 and laboratory testing personnel interview on November 5, 2020 at 8:42 AM, it was determined that the laboratory failed to follow the established schedule for testing personnel competence evaluation. The findings include: 1. The laboratory schedule for testing personnel competence evaluation showed that it must be performed every year. 2. The testing personnel records were reviewed since January 2019. 3. The testing personnel confirmed on November 5, 2020, that the laboratory director did not perform the testing personnel (MT # 1) competence evaluation since January 1, 2019.

D5421

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE
CFR(s): 493.1253(b)(1)

Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

Based on urinalysis quality control records review from January 1, 2019 to November 5, 2020 and laboratory testing personnel interview on November 5, 2020 at 10:22

AM, it was determined that the laboratory failed to perform the evaluation of the performance specifications of the Mission U 120 urinalysis system. The findings include: 1. The laboratory acquired the Mission U 120 urinalysis system and began to use on April 28, 2020. 2. The validation of the system was perform on April 28, 2020. 3. The laboratory testing personnel confirmed on November 5, 2020, that the laboratory did not perform the evaluation of the performance specifications of the Mission U 120 urinalysis system. 4. The laboratory processed and reported 224 urinalysis tests from April 28, 2020 to November 5, 2020. 5. The laboratory director did not evaluate and sign the performance specifications of the system prior to begin to test patient samples for Mission U 120 urinalysis system.

D5429

MAINTENANCE AND FUNCTION CHECKS
CFR(s): 493.1254(a)(1)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:
Based on manufacturer's written procedures, lack of urinalysis preventive maintenance records from April 28, 2020 and laboratory testing personnel interview on November 5, 2020 at 10:50 A.M., it was determined that the laboratory failed to follow written instructions for the preventive maintenance of Mission U 120 urinalysis system. The findings include: 1. The laboratory uses the Mission U 120 system to perform urinalysis tests from April 28, 2020. 2. The manufacturer's written procedures establishes that the laboratory must document and perform the routine cleaning of the test table (when required), disinfecting the test table (when required) and clean the white calibration bar (periodically check). 3. Based on lack of preventive maintenance records from April 28, 2020 to November 5, 2020, showed that the laboratory did not perform nor document the routine cleaning of the test table (when required), disinfecting the test table (when required) and clean the white calibration bar (periodically check). 4. The laboratory processed and reported 224 urinalysis patient samples from April 28, 2020 to November 5, 2020. 5. The laboratory testing personnel confirmed on November 5, 2020, that the laboratory failed to follow written instructions for the preventive maintenance of Mission U 120 system.

D6019

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(4)(iv)

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)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory.

This STANDARD is not met as evidenced by:
Based on Puerto Rico Proficiency Testing Program (PRPTP) records review from February 2019 to November 2020 and laboratory testing personnel interview on November 5, 2020 at 9:40 AM, it was determined that the laboratory director failed to

follow a corrective action plan when the laboratory obtained unsatisfactory results. The findings include: 1. Puerto Rico Proficiency Testing Program records and results were reviewed since February 2019 to November 2020. 2. Review of Proficiency Testing records showed that the laboratory obtained unsatisfactory results of 84 percent in Differential White Blood Cell for 5 parameter in July 2020 (PRPTP second testing event). No remedial actions were taken. 3. The laboratory testing personnel confirmed on November 5, 2020, that the laboratory did not take corrective actions on this testing event. Refer to D2128.

D6020

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(5)

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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:
Based on urinalysis quality control records review from January 1, 2020, manufacturer's instructions and laboratory testing personnel interview on November 5, 2020 at 11:55 AM, it was determined that laboratory director failed to ensure compliance with the requirements for analytic systems. The finding includes: 1. The laboratory director did not assure that the laboratory: a. to perform the evaluation of the performance specifications of the Mission U 120 urinalysis system. b. to follow written instructions for the preventive maintenance of Mission U 120 urinalysis system. Refer to D5421 and D5429.

D6030

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(12)

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)(12) 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 from January 2019 to November 5, 2020 and laboratory testing personnel interview on November 5, 2020 at 8:48 AM, it was determined that the laboratory director failed to follow the written procedures to monitor and ensure the competency evaluations of the testing personnel. The finding includes: 1. The personnel records showed that the laboratory director did not evaluate annually the competence of the testing personnel from January 1, 2019. Refer to D5209.