

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0668011	(X3) Date Survey Completed 02/07/2023
Name of Provider or Supplier Cdt-Cmt Group, Corp	Street Address, City, State Clemson 300 University Gardens Rio Piedras, San Juan, 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
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on review of Puerto Rico Proficiency Testing (PRPT) records (years 2021 to 2022), bacteriology patient's testing records and laboratory director interview on February 7, 2023 at 12:02 PM, it was determined that the laboratory failed to enroll in a HHS approved Proficiency Testing Program for bacteriology throat, stool, rectal and urine cultures tests when it processed and reported 796 out of 796 patients cultures specimens from July 1, 2021 to February 5, 2023. The findings include: 1. On February 7, 2023 at 12:02 PM, review the PRPT records showed no results for bacteriology throat, stool, rectal and urine cultures tests from January 2021 to December 2022. 2. On February 7, 2023 at 12:05 PM, the bacteriology patient's testing records showed that the laboratory performed the primary inoculation in the following patients cultures from July 1, 2021 to February 5, 2023: throat, stool, rectal and urine. 3. On February 7, 2023 at 12:05 PM, the bacteriology patient's testing records showed that the laboratory laboratory reported at 48 hours the following results: a. 142 out of 142 patient's throat cultures as - Abundant growth of normal throat flora. No further ID. b. 27 out of 27 patient's stool cultures as - Abundant growth of normal stool flora. No Shigella or Salmonella isolated. c. 374 out of 374</p>

patient's rectal cultures as - Abundant growth of normal rectal flora. No Shigella or Salmonella isolated, d. 133 out of 133 patient's urine cultures as - Less than 10,000 col/ml of organism isolated. No further ID. The laboratory referred the patient's cultures plates that have abnormal results for identification and susceptibility tests. 4. The laboratory director confirmed on February 7, 2023 at 12:10 PM, that the laboratory performed the primary inoculation in the following patients cultures from July 1, 2021 to February 5, 2023: throat, stool, rectal and urine and reported the colony count of the urine cultures and the normal flora for the throat, stool and rectal cultures. 5. The laboratory processed and reported 796 out of 796 patients cultures specimens from July 1, 2021 to February 5, 2023.

D2015

TESTING OF PROFICIENCY TESTING SAMPLES
CFR(s): 493.801(b)(5)(6)

(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.

This STANDARD is not met as evidenced by:
Based on Puerto Rico Proficiency Testing Program (PRPTP) records (years 2021 and 2022) review and laboratory director interview on February 7, 2023 at 1:30 PM, it was determined that the laboratory failed to maintain the attestation statements provided by the PT program, signed by the analyst and the laboratory director from February 2021 to December 2022. The findings include: 1. The PRPTP were reviewed from February 2021 to February 2022. 2. On February 7, 2023 at 1:30 PM, the PRPTP records showed that the attestation statements were not signed by the analyst nor by the laboratory from February 2021 to February 2022. 3. On February 7, 2023 at 2:19 PM, the laboratory director confirmed that the attestation statements were not signed from February 2021 to December 2022.

D5002

BACTERIOLOGY
CFR(s): 493.1201

If the laboratory provides services in the subspecialty of Bacteriology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1261, and 493.1281 through 493.1299.

This CONDITION is not met as evidenced by:
Based on review of bacteriology procedures manual, bacteriology patient's testing records(years 2021 to 2022), lack of incubator temperature chart and laboratory director interview on February 7, 2023 at 12:02 PM, it was determined that the laboratory failed to failed to ensure compliance with the analytic system requirements of bacteriology. Refer to D 5413 (The laboratory failed to follow written procedures to monitor and document daily the temperature of the bacteriology incubator when it

processed and reported 796 out of 796 patients cultures specimens from July 1, 2021 to February 5, 2023).

D5413

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(b)

The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:
Based on review of bacteriology procedures manual, bacteriology patient's testing records(years 2021 to 2022), lack of incubator temperature chart and laboratory director interview on February 7, 2023 at 12:02 PM, it was determined that the laboratory failed to follow written procedures to monitor and document daily the temperature of the bacteriology incubator when it processed and reported 796 out of 796 patients cultures specimens from July 1, 2021 to February 5, 2023. The findings include: 1. On February 7, 2023 at 12:02 PM, review of the bacteriology procedures manual showed that an incubation temperature of 35 to 37 C was required for primary inoculation procedures. 2. On February 7, 2023 at 12:04 PM, the incubator temperature chart was request to the laboratory director. The laboratory director stated that she did not have the temperature records available from July 1, 2021 to February 5, 2023. 3. On February 7, 2023 at 12:05 PM, the bacteriology patient's testing records showed that the laboratory performed the primary inoculation in the following patients cultures from July 1, 2021 to February 5, 2023: throat, stool, rectal and urine. 4. On February 7, 2023 at 12:05 PM, the bacteriology patient's testing records showed that the laboratory laboratory reported at 48 hours the following results: a. 142 out of 142 patient's throat cultures as - Abundant growth of normal throat flora. No further ID. b. 27 out of 27 patient's stool cultures as - Abundant growth of normal stool flora. No Shigella or Salmonella isolated. c. 374 out of 374 patient's rectal cultures as - Abundant growth of normal rectal flora. No Shigella or Salmonella isolated, d. 133 out of 133 patient's urine cultures as - Less than 10,000 col/ml of organism isolated. No further ID. 5. The laboratory processed and reported 796 out of 796 patients cultures specimens from July 1, 2021 to February 5, 2023.

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 instructions, Easy Lyte system preventive maintenance records (years 2022 to 2023) review and interview with the laboratory general supervisor on February 7, 2023 at 11:40 AM, it was determined that the laboratory failed to follow written instructions for the preventive maintenance of the the Easy

Lyte system when 57 out of 57 patients specimens where processed and reported for lithium (Li) test from January 2, 2022 to February 5, 2023. The findings include: 1. On February 7, 2023 at 11:40 AM, review of the manufacturer instructions showed, that the laboratory must perform the following preventive maintenance for the Easy Lyte system: a. To replace the Li electrode every six months. b. To replace the sample probe every 12 months. 2. On February 7, 2023 at 11:44 AM, Easy Lyte system preventive maintenance records showed that the laboratory did not replace the Li electrode nor replace the Easy Lyte system sample probe from January 2, 2022 to February 5, 2023. 3. On February 7, 2023 at 11:45 AM, the general supervisor confirmed that the laboratory did not perform those preventive maintenance from January 2, 2022 to February 5, 2023. 4. The laboratory processed and reported 57 out of 57 patients specimens Li test from January 2, 2022 to February 5, 2023.

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 routine chemistry quality control records review (years 2022 to 2023) and general supervisor interview on February 7, 2023 at 11:18 AM, it was determined that the laboratory failed to perform, at least every 6 months, the calibration verification procedures for the lithium (Li) test when 57 out of 57 patients specimens where processed and reported for Li by the Easy Lyte system from January 2, 2022 to February 5, 2023. The findings include: 1. On February 7, 2023 at 11:18 AM, the routine chemistry quality control records showed that the laboratory did not perform any calibration verification procedures for Li tests by the Easy Lyte system since January 2, 2022. 2. On February 7, 2023 at 11:30 AM, the laboratory general supervisor confirmed that the laboratory did not perform the calibration verification procedures for the Li tests from January 2, 2022 to February 5, 2023. 3. The laboratory processed and reported 57 out of 57 patients Li tests by the Easy Lyte system from January 2, 2022 to February 5, 2023.

D6076

LABORATORY DIRECTOR

CFR(s): 493.1441

The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.

This CONDITION is not met as evidenced by:

Based on review PRPT, bacteriology testing records, bacteriology and routine chemistry quality control records, laboratory director and general supervisor interview on February 7, 2023 at 12:02 PM, it was determined that the laboratory director failed to fulfill her responsibilities and duties to ensure compliance with the laboratory Proficiency Testing and quality control requirements. Refer to D 6088 Based on review of Puerto Rico Proficiency Testing (PRPT) records (years 2021 to 2022), bacteriology patient's testing records and laboratory director interview on February 7, 2023 at 12:02 PM, it was determined that the laboratory director failed to ensure that the is enrolled in a HHS approved Proficiency Testing Program for bacteriology throat, stool, rectal and urine cultures tests. Refer to D 6089 Based on Puerto Rico Proficiency Testing Program (PRPTP) records (years 2021 and 2022) review and laboratory director interview on February 7, 2023 at 1:30 PM, it was determined that the laboratory director failed to maintain the attestation statements provided by the PT program, signed by the analyst and by her from February 2021 to December 2022. Refer to D 2016. Refer to D 6093 Based on review of bacteriology procedures manual, bacteriology patient's testing records, lack of incubator temperature charts, manufacturer's instructions and Easy Lyte system preventive maintenance records and interview with the laboratory director, general supervisor and testing personnel on February 7, 2023 at 12:02 PM, it was determined that the laboratory director failed to ensure compliance with the analytic system requirements for the Bacteriology and Routine Chemistry specialties.

D6088

LABORATORY DIRECTOR RESPONSIBILITIES

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

The laboratory director must 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 review of Puerto Rico Proficiency Testing (PRPT) records (years 2021 to 2022), bacteriology patient's testing records and laboratory director interview on February 7, 2023 at 12:02 PM, it was determined that the laboratory director failed to ensure that the is enrolled in a HHS approved Proficiency Testing Program for bacteriology throat, stool, rectal and urine cultures tests from July 1, 2021 to February 5, 2023. The findings include: 1. The laboratory was not enroll in a PT Program for Bacteriology subspecialty. Refer to D 2000. 2. During the interview on February 7, 2023 at 12:05 PM, the laboratory director stated that she was in charge of the laboratory proficiency enrollment procedure.

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 Testing Program (PRPTP) records (years 2021 and 2022) review and laboratory director interview on February 7, 2023 at 1:30 PM, it was determined that the laboratory director failed to maintain the attestation statements provided by the PT program, signed by the analyst and by her from February 2021 to December 2022. Refer to D 2015.

D6093

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:
Based on review of bacteriology procedures manual, bacteriology patient's testing records, lack of incubator temperature charts, manufacturer's instructions, Easy Lyte system preventive maintenance records and interview with the laboratory director, general supervisor and testing personnel on February 7, 2023 at 12:02 PM, it was determined that the laboratory director failed to ensure compliance with the analytic system requirements for the Bacteriology, Hematology and Routine Chemistry specialties. Refer to D 5002 (The laboratory failed to failed to ensure compliance with the analytic system requirements of bacteriology). Refer to D 5429 (The laboratory failed to follow written instructions for the preventive maintenance of the the Easy Lyte system from January 2, 2022 to February 5, 2023). Refer to D 5439 (The laboratory failed to perform at least every 6 months the calibration verification procedures for the Li tests by the Easy Lyte system from January 2, 2022 to February 5, 2023).

D6144

GENERAL SUPERVISOR RESPONSIBILITIES

CFR(s): 493.1463

The general supervisor is responsible for day-to-day supervision or oversight of the laboratory operation and personnel performing testing and reporting test results.

This STANDARD is not met as evidenced by:
Based on review of quality control records and interview with the laboratory personnel on February 7, 2023 at 12:02 PM, it was determined that the general supervisor did not assure that the testing personnel followed the established quality control procedures for Li tests and the Easy Lyte preventive maintenance. The findings includes: 1. No calibration verification procedure for Li test were performed during year 2022 (Refer to D 5439). 2. No preventive maintenance instructions were followed for the Easy Lyte instrument since January 2, 2022 (Refer to D 5429).