| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 40D0865451 | 03/13/2026 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Post Center Clinical Laboratory | 60 North Post St Edif Post Ctr Of 105, Mayaguez, 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 |
|---|---|
| **D0000** | A recertification survey was conducted on March 13, 2026, Inmediate Jeopardy exist for the following conditions : D5002-42 C.F.R 493.1201 Condition : Bacteriology D6076-42 C.F.R 493.1441 Condition : Laboratory Director, high complexity. |
| **D3039** | RETENTION REQUIREMENTS<br>CFR(s): 493.1105(a)(5)<br><br>(a)(5) Quality system assessment records. Retain all laboratory quality system assessment records for at least 2 years.<br><br>This STANDARD is not met as evidenced by:<br>Based on lack of Quality Assessment (QA) records and laboratory general supervisor interview on March 13, 2026 at 1:20 p.m., that the laboratory did not perform the evaluations of the Quality Assessment Program in order to monitor and evaluate the laboratory activities (general system, pre-analytic, analytic and post-analytic systems) since December 2024. The findings include: 1. The laboratory did not evaluate the established Quality Assessment program since December 2024. 2. The laboratory general supervisor confirmed on March 13, 2026 at 1:20 p.m., that the laboratory did not evaluate nor document the established Quality Assessment program in the laboratory since December 2024. |
| **D5002** | BACTERIOLOGY<br>CFR(s): 493.1201<br><br>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:<br>Based on Bacteriology quality control records review ( year 2025-2026 ) and lack of bacteriology quality control on March 13, 2026 at 1:15 p.m.the laboratory failed to be in compliance with the bacteriology analytic system requirements . Refer to D5401, D5403, D5413, D5429 and D5441. |
| **D5209** | PERSONNEL COMPETENCY ASSESSMENT POLICIES<br>CFR(s): 493.1235<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on personnel competence records review (years 2024-2026) and laboratory supervisor interview on March 13, 2026 at 10: 25 AM, the laboratory failed to follow the established schedule for competency evaluation for the technical supervisor, general supervisor, technical consultant, clinical consultant and medical technologist. The finding includes: 1. On March 13, 2026 at 10: 25 AM, the laboratory written policies for personnel competency procedures showed that the competency procedures must be performed annually. 2. The laboratory technical supervisor was designated as general supervisor, technical consultant, and medical technologist. The competence records showed that the laboratory did not evaluate the personnel competency since December 2024. 3. The clinical consultant competency was not evaluated since December 2024. 4. During the interview on March 13, 2026 at 10: 25 AM, the laboratory supervisor confirmed that the technical supervisor, general supervisor, technical consultant, medical technologist and clinical consultant competency evaluation were not performed. |
| **D5291** | GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT<br>CFR(s): 493.1239(a)<br><br>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.<br><br>This STANDARD is not met as evidenced by:<br>Based on Quality Assessment (QA) activities, bacteriology IQCP, QA work sheets records review ( year 2024-2025) and laboratory general supervisor interview on March 13, 2026 at 1:15 p.m. the laboratory failed to evaluate and monitor the General Laboratory system requirements. The findings include: 1. On March 13, 2026 at 1:15 p.m. the laboratory general system QA activities, since December 2024 , were requested. 2. The QA records showed that the laboratory failed to evaluate the following QA activities : a. patient confidentiality- since December 13, 2024. b. specimen identification - since November 6, 2024. c. specimen integrity- since December 13, 2024. d. communications - since 12/13/2024 e.personnel competence- since 12/17/2024 3. On March 13, 2026 at 1:00 p.m. QA activities related to the bacteriology IQCP were requested. The reviewed QA worksheets showed that the evaluation must be performed every month. The last evaluation was performed on August 2025. 4. The laboratory general supervisor confirmed on March 13, 2026 at 1: |

| | |
|---|---|
| | 15 p.m. that the laboratory failed to monitor the general laboratory systems practices related to: patient confidentiality, specimen identification and integrity, personnel competence and communications since December 2024. |
| **D5391** | PREANALYTIC SYSTEMS QUALITY ASSESSMENT<br>CFR(s): 493.1249(a)<br><br>(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems specified at 493.1241 through 493.1242.<br><br>This STANDARD is not met as evidenced by:<br>Based on Quality Assessment (QA) activities records review (year 2024-2025) and laboratory general supervisor interview on March 13, 2026 at 1:15 p.m. the laboratory failed to evaluate and monitor the pre analytic system requirements. The findings include: 1. The QA records showed that the laboratory failed to evaluate the following pre-analytic QA activities : medical order - since December 2, 2024. 2. The laboratory general supervisor confirmed on March 13, 2026 at 1:15 p.m.that the laboratory failed to monitor the medical order since December 2,2024. |
| **D5401** | PROCEDURE MANUAL<br>CFR(s): 493.1251(a)<br><br>(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.<br><br>This STANDARD is not met as evidenced by:<br>Based on review on March 13, 2026 at 12:45 p.m. of the bacteriology IQCP and interview with the laboratory general supervisor, the laboratory did not follow written procedures established for the bacteriology IQCP. The findings include: 1. The IQCP written plan showed that the laboratory must review the implemented plan, each year. There were no review of the IQCP since the implementation date on March 2020. 2. Review of the quality control records showed that the laboratory did not follow the implemented culture media control plan and not the daily incubator temperature record . Refer to D5441. 3. During interview with the general supervisor,she acknowledge the deficient practices. |
| **D5403** | PROCEDURE MANUAL<br>CFR(s): 493.1251(b)<br><br>(b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as |

| | |
|---|---|
| | established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable.<br><br>This STANDARD is not met as evidenced by:<br>Based on bacteriology procedure manual, incubator temperature sheets and laboratory general supervisor interview on March 13, 2026 at 9:50 a.m.,the bacteriology procedure manual did not include a reference of the required incubation temperature for the culture plate used for patient testing. The findings include: 1. At 8:57 a.m.on March 13, 2026 the laboratory bacteriology incubator temperature record sheet was reviewed. The sheet showed an incubator temperature range of 35 +/- 3 C. 2. Review of the bacteriology procedure manual at 9:50 a.m. on March 13, 2026 showed that no reference of the required incubation temperature for the culture required incubation temperature was included. 3.The laboratory general supervisor confirmed on March 13, 2026 at 1:00 p.m. the bacteriology procedure manual did not include a reference of the required incubation temperature for the culture plate used for patient testing. |
| **D5405** | PROCEDURE MANUAL<br>CFR(s): 493.1251(c)<br><br>(c) Manufacturer's test system instructions or operator manuals may be used, when applicable, to meet the requirements of paragraphs (b)(1) through (b)(12) of this section. Any of the items under paragraphs (b)(1) through (b)(12) of this section not provided by the manufacturer must be provided by the laboratory.<br><br>This STANDARD is not met as evidenced by:<br>Based on Mycoplasma Pneumoniae IgM test quality control records review ( year 2025 ) , manufacturer's instructions review, and laboratory supervisor interview on March 13, 2026 at 12:40 p.m., the laboratory failed to monitor and document the room temperature, when 3 patient specimens were processed and reported for Mycoplasma pneumoniae IgM test on 11/26/25, 12/1/25 and 12/5/25. The findings include: a. The laboratory uses the Immuno Card Mycoplasma kit to perform the Mycoplasma pneumoniae IgM tests. b. On March 13, 2026 at 12:40 p.m., the manufacturer's instructions were reviewed, and it establishes to perform the test procedures at room temperature from 22 to 25  c. On March 13, 2026 at 12:40 p.m., review of the Mycoplasma pneumoniae IgM quality control records showed that the laboratory did not monitor nor document the room temperature when patient's specimens were tested for Mycoplasma pneumoniae IgM on 11/26/25, 12/1/25 and 12/5/25. d. The laboratory supervisor confirmed on March 13, 2026 at 12:40 p.m., that the laboratory did not monitor nor document the room temperature when they processed the patient's specimens for Mycoplasma pneumoniae IgM test. e. The laboratory processed and reported three (3) patient samples for Mycoplasma pneumoniae IgM test on 11/26/25, 12/1/25 and 12/5/25. |
| **D5413** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT |

| | |
|---|---|
| | CFR(s): 493.1252(b)<br><br>(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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.<br><br>This STANDARD is not met as evidenced by:<br>1. Based on bacteriology daily room temperature , relative humidity , incubator temperature documentation sheet and patient worksheets review on March13, 2025 at 8:57 a.m.and laboratory general supervisor interview, the laboratory did not monitor nor document the daily room temperature , relative humidity and incubator temperature since August 8, 2025. The laboratory performed and reported 431 throat culture and 107 urine culture since August 8, 2025 to March 13, 2026. The findings include: a. On March 13,2026 at 8:57 a.m. the bacteriology room temperature, humidity and incubator temperature record sheet was requested, the record showed that the laboratory did not document any temperature or humidity percentage since August 5, 2025. b. The laboratory general supervisor confirmed on March 13, 2026 at 9: 50 a.m. that the laboratory failed to monitor and document the daily the room temperature , relative humidity and incubator temperature since August 8, 2025. c. Review of the patients worksheets on March 13, 2026 at 10:15 a.m.showed that the laboratory performed and reported 431 throat culture and 107 urine culture since August 8, 2025 to March 13, 2026. 2. Based on bacteriology incubator preventive maintenance worksheet reviewed on March 13, 2026 at 9:58 a.m. ( year 2025-2026 ) and laboratory general supervisor interview, the laboratory failed to perform the weekly preventive maintenance ( cleaning ) of the incubator since August 5, 2025. The findings include: 1. Review of the bacteriology incubator preventive maintenance procedure manual sheet showed that the laboratory must clean the instrument on a weekly basis. 2. During the survey perform on March 13, 2026, the preventive maintenance worksheet showed that the laboratory did not perform the preventive maintenance of the bacteriology incubator since August 5, 2025. 3. The laboratory general supervisor confirmed on March 13, 2026 at 1:00 p.m. that the laboratory failed to perform the preventive maintenance of the bacteriology incubator since August 5, 2025. |
| **D5429** | MAINTENANCE AND FUNCTION CHECKS<br>CFR(s): 493.1254(a)(1)<br><br>(a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.<br><br>This STANDARD is not met as evidenced by:<br>Based on laboratory peripherals instruments observation and laboratory general supervisor interview on March 13, 2026 at 9:58 a.m., the laboratory did not perform the annual preventive maintenance check of the following : microscope, centrifuge, bacteriology room area thermometer, bacteriology incubator and syphilis serology rotator since August 5, 2024. The finding include: 1. On March 13, 2026 at 1:00 p.m. |

| | |
|---|---|
| | the peripheral equipment certification seals showed that the last recorded certification date was on August 5, 2024. The laboratory did not have any other records for peripheral equipment maintenance other than the equipment seals. 2. The laboratory general supervisor confirmed on March 13, 2026 at 1:00 p.m. that the laboratory failed to perform the annual preventive maintenance of the following equipment : microscope, centrifuge, bacteriology room area thermometer, bacteriology incubator and syphilis serology rotator since August 5, 2024. |
| **D5441** | CONTROL PROCEDURES<br>CFR(s): 493.1256(a)(b)(c)(g)<br><br>(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance.<br><br>This STANDARD is not met as evidenced by:<br>1. Based on review of the bacteriology Individualized quality control plan ( IQCP ) dated March 2020 and lack of quality control records, the laboratory did not follow the quality control plan established for the blood agar and MacConkey culture plates media. The findings include: a. Review of the blood agar and MacConkey culture plates media. quality control plan, established that the laboratory verify the culture media of each lot received. b. The laboratory did not have any quality control records for blood agar and MacConkey culture media. c. The laboratory performed and reported 431 throat culture and 107 urine culture since August 8, 2025 to March 13, 2026. 2. Based on review of Bacteriology IQCP, quality control plan and interview with the laboratory general supervisor on March 13, 2026 at 1:30 p/. , the laboratory did not follow the established control plan for the bacteriology incubator. The finding include: a. Review of the bacteriology quality control plan showed that the bacteriology incubator thermometer must be monitored and registered daily. b Review of the bacteriology incubator temperature chart on March 13, 2026 at 8:57 a.m. showed that the laboratory did not monitor the incubator temperature since August 5, 2025. c. The laboratory general supervisor confirmed on March 13, 2026 at 1:00 p.m. that the laboratory failed to monitor the incubator temperature since August 5, 2025. |
| **D5449** | CONTROL PROCEDURES<br>CFR(s): 493.1256(d)(3)(ii)(g)<br><br>(d)(3)(ii) Each qualitative procedure, include a negative and positive control material;<br><br>This STANDARD is not met as evidenced by:<br>Based on the Mycoplasma pneumoniae IgM quality control records review ( year 2025 ) , and laboratory general supervisor interview on March 13, 2026 at 12:36 p.m., the laboratory failed to include an external negative and positive control material , each day of patient testing. The laboratory processed and reported three (3) patient samples on 11/26/25, 12/1/25 and 12/5/25. The findings include: 1. The laboratory |

| | |
|---|---|
| | uses the Immuno Card Mycoplasma kit to perform the Mycoplasma pneumoniae IgM tests. 2. Review of the Mycoplasma pneumoniae IgM test quality control records on March 13, 2026 at 12:36 p.m., showed that the laboratory did not perform the external negative and positive control material each day of patient testing. 3. The laboratory general supervisor confirmed on March 13, 2026 at 12:36 p.m., that the laboratory failed to perform the external negative and positive control material each day of patient testing when the laboratory processed and reported 3 patient samples on 11/26 /25, 12/1/25 and 12/5/25. |
| **D5791** | ANALYTIC SYSTEMS QUALITY ASSESSMENT<br>CFR(s): 493.1289(a)(c)<br><br>(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283.<br><br>This STANDARD is not met as evidenced by:<br>Based on the review of the Quality Assessment (QA) records ( 2024 ) and interview with the laboratory general supervisor on March 13, 2026 at 1:30 p.m.; it was determined that the laboratory failed to monitor the analytic systems activities related to: test procedures, test systems, equipment, instruments, systems maintenance since December 2024. Refer to D5401, D5403, D5405, D5413 , D5429 , D5441 and D5449. |
| **D5891** | POSTANALYTIC SYSTEMS QUALITY ASSESSMENT<br>CFR(s): 493.1299(a)<br><br>(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291.<br><br>This STANDARD is not met as evidenced by:<br>Based on Quality Assessment (QA) activities records review ( year 2024-2025) and laboratory general supervisor interview on March 13, 2026 at 1:15 p.m. the laboratory failed to evaluate and monitor the post- analytic laboratory system requirements. The findings include: 1. On March 13, 2026 at 1:15 p.m. the laboratory post- analytic QA activities, since December 2024 ,were requested. 2. The QA records showed that the laboratory failed to evaluate the following QA activities : turn around time ( TAT ) - since 12/13/2024 test report evaluation- since 12/6/2024 3. The laboratory general supervisor confirmed on March 13, 2026 at 1:15 p.m.that the laboratory failed to monitor the post analytic systems practices since December 2024. |
| **D6076** | LABORATORY DIRECTOR<br>CFR(s): 493.1441<br><br>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.<br><br>This CONDITION is not met as evidenced by:<br>Based on bacteriology quality control records reviewed ( 2025-2026), lack of |

| | |
|---|---|
| | bacteriology quality control records, PRPTP records ( 2024-2025 ) and laboratory general supervisor interview on March 13, 2026 at 1:30 P.M., the laboratory director failed to fulfill his responsibilities and duties to ensure compliance with the laboratory analytical system requirements. Refer to D6093. |
| **D6093** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(5)<br><br>(e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;<br><br>This STANDARD is not met as evidenced by:<br>Based on lack of bacteriology quality control records review (year 2024-2025 ) bacteriology quality control records ,QA evaluations and interview with the laboratory general supervisor on March 13, 2026 at 1:15 P.M. the laboratory director failed to ensure the compliance with the analytic and quality assessment rquirements. Refer to D5291, D5391, D5401, D5403, D5405, D5413 D5429, D5441, D5449, D5791 and D5891. |
| **D6144** | GENERAL SUPERVISOR RESPONSIBILITIES<br>CFR(s): 493.1463<br><br>The general supervisor is responsible for day-to-day supervision or oversight of the laboratory operation and personnel performing testing and reporting test results.<br><br>This STANDARD is not met as evidenced by:<br>Based on bacteriology area quality control review ( 2025 ) and interview with the laboratory supervisor on March 13, 2026 at 1:20 P.M; it was determined that the laboratory supervisor failed to carry out successful day to day supervision in the bacteriology area. Refer to D5403, D5405, D5413, D5429, D5449. |