

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  40D2026062	<b>(X3) Date Survey Completed</b>  06/27/2023
<b>Name of Provider or Supplier</b>  Aguada Medical Center	<b>Street Address, City, State</b>  Road 115 Km 24 Hm 5 Barrio Asomante, Aguada, PR	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2009</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> 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 Program (PRPTP) records review (year 2022-2023), and laboratory supervisor interview on June 27,2023 at 10:08 AM, it was determined that the laboratory director failed to sign the attestation statements. The findings include: 1. Puerto Rico Proficiency testing records were reviewed from February 2022 to June 2023. (Reviewed on June 27,2023 at 10:08 AM). 2. The Puerto Rico Proficiency Testing records review showed that the laboratory director or designee did not sign the attestation statements from February 2023 to June 2023. (Reviewed on June 27,2023 at 10:19 AM). 3. The laboratory supervisor confirmed on June 27,2023 at 10:31 AM, that the laboratory director failed to sign the attestation statement from February 2023 to June 2023.</p>
<b>D5020</b>	<p><b>ENDOCRINOLOGY</b> CFR(s): 493.1212</p> <p>If the laboratory provides services in the subspecialty of Endocrinology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, and 493.1281 through 493.1299.</p> <p>This CONDITION is not met as evidenced by: Based on serum Human Chorionic Gonadotropin (hCG) test quality control records</p>

(years 2022 to 2023) and interview with the laboratory director and laboratory general supervisor on June 27, 2023 at 1:00 PM, it was determined that the laboratory failed to ensure compliance with the analytic system requirements for serum hCG qualitative tests. The finding includes: 1. The human chorionic gonadotropin (hCG) test quality control records (years 2022 to 2023) showed that the laboratory did not include each day of testing a negative and a positive control material when patients specimens were processed and reported for serum hCG qualitative test. Refer to D 5401.

**D5401**

**PROCEDURE MANUAL**  
CFR(s): 493.1251(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.

This STANDARD is not met as evidenced by:

Based on endocrinology quality control records (year 2022-2023), patient's test reports, laboratory written instructions review and laboratory supervisor interview on June 27, 2023, at 1:00 PM, it was determined that the laboratory did not follow the written procedures related to the human chorionic gonadotropin (hCG) quality control procedures, when they performed and reported 53 out of 58 hCG patient's test from January 2, 2023, to June 22, 2023. The findings include: 1. The laboratory performed hCG patient's test by Alere hCG cassette. (Reviewed on June 27,2023 at 1:00 PM). 2. Reviewed the human chorionic gonadotropin (hCG) written instructions, showed that the laboratory must include an external negative and positive control material, on each work shift. Reviewed on June 27,2023 at 1:01 PM). 3. The endocrinology quality control and patient's test reports were reviewed from January 2022 to June 2023. (Reviewed on June 27,2023 at 1:02 PM). 4. The endocrinology quality control showed that the laboratory did not include an external negative and positive control material, each testing day, from January 2, 2023, to June 22, 2023. The laboratory only documented the internal procedure control with each patient. (Reviewed on June 27,2023 at 1:05 PM). 5. The laboratory supervisor confirmed that the laboratory did not include an external and positive control material each day of testing. (Reviewed on June 27,2023 at 1:10 PM). 6. The laboratory performed and reported 53 out of 58 patient's specimen were tested for hCG from January 2, 2023, to June 22, 2023.

**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 performance specifications records review (year 2023) for the amylase and lipase tests, laboratory patient's worklist and laboratory director interview on June

27,2023 at 12:30 PM, it was determined that the laboratory director did not review, evaluate, and approve the amylase and lipase performance specifications tests since March 2023. The findings include: 1. The laboratory performed routine chemistry test in Medica Easy RA. (Reviewed on June 27,2023 at 12:30 PM). 2. The laboratory performed the performance verification for amylase and lipase test in March 2023. The performance verification records were not signed by the laboratory director. (Reviewed on June 27,2023 at 12:32 PM). 3. The laboratory patients worklist showed that since March 2023, the laboratory processed and reported ten (10) amylase test and eleven (11) lipase patient's test. (Reviewed on June 27,2023 at 12:35 PM). 4. The laboratory director confirmed that it failed to review, evaluate, and approve the amylase and lipase performance specifications prior to begin to test patient samples. (Reviewed on June 27,2023 at 12:44 PM).

**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 (years 2021-2023), laboratory written instructions review and laboratory supervisor interview on June 27, 2023, at 12:00 PM, it was determined that the laboratory failed to perform the calibration verification procedures at the frequency established by the laboratory. The findings include: 1. The laboratory used the Sysmex XN-21 Hematology system for CBC (Complete blood count) patient's tests. (Reviewed on June 27,2023 at 12:00 PM). 2. The laboratory written instruction showed that the calibration verification procedures must be performed each six (6) months. (Reviewed on June 27,2023 at 12:04 PM). 3. From June 2021 to May 2, 2023, the records showed that the laboratory did not perform, at least every six (6) months, the calibration verification procedures for the Sysmex XN-21 Hematology system. The calibration verification procedures were performed in May 2021 and May 3, 2023. The laboratory did not perform the calibration verification procedures scheduled for November 2021, May 2022 and November 2022. (Reviewed on June 27,2023 at 12:08 PM). 4. The laboratory processed and reported 5,394 Complete blood count (CBC) patient's samples from June 2021 to May 2, 2023. 5. The laboratory supervisor confirmed on June 27, 2023, at 12:15 PM, that the laboratory did not perform at least every six (6) months the calibration verification procedures for the Sysmex XN-21 Hematology system.

**D5449**

**CONTROL PROCEDURES**

CFR(s): 493.1256(d)(3)(ii)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--

At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:  
Based on general immunology (Mycoplasma pneumoniae test) quality control records (year 2023), patient's reports review and laboratory supervisor interview on June 27, 2023, at 1:30 PM, it was determined that the laboratory did not include an external negative and positive control material each testing day when performed and reported 23 out of 24 Mycoplasma pneumoniae patient test from March 10, 2023, to June 21, 2023. The findings include: 1. The laboratory performed Mycoplasma pneumoniae patient's test by Immunocard method. (Reviewed on June 27,2023 at 1:30 PM). 2. The general immunology (Mycoplasma pneumoniae test) quality control and patient's report were reviewed from March 2023 to June 2023. (Reviewed on June 27,2023 at 1: 32 PM). 3. The general immunology (Mycoplasma pneumoniae test) quality control showed that the laboratory did not include an external negative and positive control material each testing day from March 10, 2023, to June 21, 2023. (Reviewed on June 27,2023 at 1:35 PM). 4. The laboratory supervisor confirmed that the laboratory did not include an external negative and positive control material each day of testing. The laboratory included the internal procedure control with each patient (Reviewed on June 27,2023 at 1:40 PM). 5. The laboratory reported and performed 23 out of 24 patient's specimen were tested for Mycoplasma pneumoniae from March 10, 2023, to June 21, 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 endocrinology quality control (year 2022-2023) and laboratory general supervisor interview on June 27,2023 at 1:10 PM, it was determined that the laboratory director failed to fulfill his responsibilities and duties to ensure compliance with the laboratory quality control. Refer to D6086 and D6093.

**D6086**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1445(e)(3)(ii)

The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method.

This STANDARD is not met as evidenced by:  
Based on performance specifications records for the amylase and lipase test on June 27,2023 at 12:45 PM, it was determined that laboratory director failed to review, evaluate, and approve the amylase and lipase performance specifications prior to begin to test patient samples. Refer to D5421.

**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 quality control records and interview with the laboratory director on June 27, 2023, at 1:40 PM, it was determined that the laboratory director did not make sure that the technical supervisor maintained the quality control requirements for human chorionic gonadotropin (hCG) and Mycoplasma pneumoniae patient test. The findings include: 1. The laboratory did not follow written instructions for hCG quality control. (Refer to D5401) 2. The laboratory did not include an external control material for Mycoplasma pneumoniae each day of testing. (Refer to D5449)

**D6117**

**TECHNICAL SUPERVISOR RESPONSIBILITIES**

CFR(s): 493.1451(b)(4)

The technical supervisor is responsible for establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results.

This STANDARD is not met as evidenced by:

Based on quality control records (year 2022-2023) and the technical supervisor interview on June 27, 2023 at 1:50 PM, it was determined that the technical supervisor did not ensure that the testing personnel follow the written instructions control procedures for the hCG and Mycoplasma pneumoniae patient test. (Refer to D5401 and D5449)