

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  40D0658241	<b>(X3) Date Survey Completed</b>  08/24/2023
<b>Name of Provider or Supplier</b>  Ashford Medical Laboratory	<b>Street Address, City, State</b>  Edificio Ashford Medical Suite 210 Condado, San Juan, 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 Program testing records review (years 2022 and 2023) and laboratory supervisor interview on August 24, 2023, it was determined that the laboratory director and testing personnel failed to sign the proficiency attestation statements. The findings include: 1. Puerto Rico Proficiency testing records from years 2022 and 2023 were reviewed on August 24, 2023 at 1:00 PM 2. On August 24, 2023 at 1:30 pmhe attestation statements (submission form page 10) instructed the laboratory to print, fill, sing and retain the page for laboratory records and inspection purposes. Review of the attestation statements forms from years 2022 and 2023, showed that none of them were signed by director nor the individual who tested the samples. 3. On August 24, 2023 at 1:40 pm, the supervisor stated that the attestation statements were never signed by the personnel.</p>
<b>D5291</b>	<p><b>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT</b> CFR(s): 493.1239(a)</p> <p>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.</p>

This STANDARD is not met as evidenced by:  
Based on lack of Quality Assessment (QA) activities records (years 2022 to 2023 ) and interview with the laboratory supervisor on August 24, 2023 n November 15, 2022 , it was determined that laboratory failed to evaluate and monitor the General Laboratory system requirements . The findings include: a. On August 24, 2023 at 2:45 PM, the laboratory supervisor was interviewed regarding the QA program activities. The supervisor stated that the QA activities for year 2022 were not available. For year 2023, she stated that she was recollecting the information for later evaluation, however no evaluation was performed. b. The laboratory did not have any evaluations related to: Patient confidentiality, specimen identification and integrity, compliant investigation, communications and personnel competency. c. At 2:55 pm the QA manual was requested to the laboratory supervisor, she stated that the QA procedure manual was not available at the laboratory.

**D5391**

**PREANALYTIC SYSTEMS QUALITY ASSESSMENT**  
CFR(s): 493.1249(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.

This STANDARD is not met as evidenced by:  
Based on lack of Quality Assessment (QA) activities records (years 2022 to 2023 ) and interview with the laboratory supervisor on August 24, 2023 , it was determined that laboratory failed to evaluate and monitor the Preanalytic Laboratory system requirements . The findings include: a. On August 24, 2023 at 2:45 PM, the laboratory supervisor was interviewed regarding the QA program activities. The supervisor stated that the QA activities for year 2022 were not available. For year 2023, she stated that she was recollecting the information for later evaluation, however no evaluation was performed. b. The laboratory did not have any evaluations related to: test requests, specimen submission, handling and referral. c. At 2:55 pm the QA manual was requested to the laboratory supervisor, she stated that the QA procedure manual was not available at the laboratory.

**D5791**

**ANALYTIC SYSTEMS QUALITY ASSESSMENT**  
CFR(s): 493.1289(a)(c)

(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. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:  
Based on lack of Quality Assessment (QA) activities records (years 2022 to 2023 ) and interview with the laboratory supervisor on August 24, 2023 , it was determined that laboratory failed to evaluate and monitor the Analytic Laboratory system requirements . The findings include: a. On August 24, 2023 at 2:45 PM, the laboratory supervisor was interviewed regarding the QA program activities. The supervisor stated that the QA activities for year 2022 were not available. For year 2023, she stated that she was recollecting the information for later evaluation, however no evaluation was performed. b. The laboratory did not have any evaluations related to:

	<p>test procedures, accurate and reliable test systems, specimen and reagent storage conditions, equipment/instruments/test system maintenance and function checks, calibration and calibration verification, control procedure, comparison of test results, corrective actions and test records. c. At 2:55 pm the QA manual was requested to the laboratory supervisor, she stated that the QA procedure manual was not available at the laboratory.</p>
<p><b>D5891</b></p>	<p><b>POSTANALYTIC SYSTEMS QUALITY ASSESSMENT</b> CFR(s): 493.1299(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on lack of Quality Assessment (QA) activities records (years 2022 to 2023 ) and interview with the laboratory supervisor on August 24, 2023 , it was determined that laboratory failed to evaluate and monitor the Post analytic Laboratory system requirements . The findings include: a. On August 24, 2023 at 2:45 PM, the laboratory supervisor was interviewed regarding the QA program activities. The supervisor stated that the QA activities for year 2022 were not available. For year 2023, she stated that she was recollecting the information for later evaluation, however no evaluation was performed. b. The laboratory did not have any evaluations related to: test reports, turn around time and communications. c. At 2:55 pm the QA manual was requested to the laboratory supervisor, she stated that the QA procedure manual was not available at the laboratory.</p>
<p><b>D6076</b></p>	<p><b>LABORATORY DIRECTOR</b> CFR(s): 493.1441</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on lack lack of quality assessment and laboratory supervisor interview on August 24, 2023, it was determined that the laboratory director failed to fulfill his responsibilities and duties to ensure compliance with the laboratory quality assessment requirements. The finding includes: 1. The laboratory did not have available a quality assessment manual and did not evaluate the general, pre-analytic, analytic or post-analytic systems since year 2022 Refer to D6094</p>
<p><b>D6094</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1445(e)(5)</p> <p>The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on Quality Assessment (QA) records review and laboratory supervisor interview on August 24, 2023, it was determined that laboratory director failed to ensure compliance with quality assessment (QA) requirements. The finding includes:

- a. Due to lack of a QA written program, it was determined that the laboratory director did not established not mantained, a Quality Assessment Program to monitor and evaluate the requirements for general, preanalytic, analytic not post-analytic systems. Refer to D 5291, D5491, D5791 and D5891.