

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D1049621	(X3) Date Survey Completed 06/17/2022
Name of Provider or Supplier Oficina Dr Jose A Lozada Costas	Street Address, City, State Adler Medical Plaza #576 Suite 503, 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
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 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.</p> <p>This STANDARD is not met as evidenced by: Based on Puerto Rico Proficiency Testing Program records review(years 2020, 2021 and 2022) and Physician Office Laboratory director (POL) interview on June 17, 2022, it was determined that the POL failed to take and document corrective actions when it obtained an unsatisfactory results for hematology specialty in the thirds testing event of year 2021 and in the first testing event of year 2022. The findings include: 1. Puerto Rico Proficiency Testing Program records were reviewed from from year 2020 to 2022. 2. The laboratory participates in the Puerto Rico Proficiency Testing Program (PRTP) for hematology cell identification testing. 3. On June 17, 2022 at 10:30 am, the PRTP records showed that the POL obtained a 0 per cent result for Cell Identification proficiency testing in November 2021 and a 60 per cent result in April 2022. However , no corrective actions were taken no documented. 4. The POL director confirmed on June 17, 2022 at 10:35 am, that no corrective actions were taken nor documented. He also stated that the POL did not receive the proficiency testing sample for November 2021 event.</p>
D3039	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(5)</p>

Quality system assessment records. Retain all laboratory quality system assessment records for at least 2 years.

This STANDARD is not met as evidenced by:

Based on lack of quality assessment (QA) records and interview with the POL director on June 17, 2022, it was determined that the POL failed to retain the QA records (general laboratory system, pre-analytic, analytic and post-analytic systems) from January 9, 2021 to June 17, 2022. The findings included: 1. On June 17, 2022 at 9:38 am, the POL did have the QA record available in the POL: general laboratory system, pre-analytic system, analytic system and post-analytic systems from January 9 2021 to June 17, 2022. 2. On June 17, 2022 at 9:45 am, the POL director confirmed on June 17, 2022 at 9:45 am, that those QA records were not available.

D6079

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(a)(b)

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, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reappoints performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:

Based on lack of QA records and interview with the POL director on June 17, 2022, it was determined that the POL failed to retain the QA records for at least 2 years. Refer to D 3039 (The POL failed to retain the QA records from January 9, 2021 to June 17, 2022).

D6091

LABORATORY DIRECTOR RESPONSIBILITIES

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

The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action.

This STANDARD is not met as evidenced by:

Based on Puerto Rico Proficiency Testing Program records review (years 2020, 2021 and 2022) and Physician Office Laboratory director (POL) interview on June 17, 2022, it was determined that the POL director failed did not ensure that corrective actions were taken when the POL obtained unsatisfactory proficiency testing results. Refer to D 2128 (The POL did not take nor document corrective actions when it obtained an unsatisfactory results for hematology specialty).