

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  40D0666528	<b>(X3) Date Survey Completed</b>  02/03/2023
<b>Name of Provider or Supplier</b>  Imrl Clinical Lab	<b>Street Address, City, State</b>  Calle Domingo Caceres #11e, Carolina, 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>D3039</b>	<p><b>RETENTION REQUIREMENTS</b> CFR(s): 493.1105(a)(5)</p> <p>Quality system assessment records. Retain all laboratory quality system assessment records for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on Quality Assessment (QA) records review (years 2020 and 2021) and laboratory director interview by telephone call, during the onsite survey on February 3, 2023 at 12:10 PM, it was determined that the laboratory failed to retain the Quality Assessment records (annual evaluations for the following systems: pre-analytic, analytic and post-analytic systems since November 2020. The findings include: 1. On February 3, 2023 at 12:10 PM, the QA records showed that the laboratory did not maintain the annual evaluations of the Quality Assessment Program Program (pre-analytic, analytic and post-analytic systems) since November 2020. 2. On February 3, 2023 at 12:20 PM, the laboratory director confirmed that the annual evaluations of the QA program were not available in the laboratory since November 2020.</p>
<b>D6079</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1445(a)(b)</p> <p>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</p>

properly performed.

This STANDARD is not met as evidenced by:

Based on Quality Assessment (QA) records review (years 2020 and 2021) and laboratory director interview by telephone call on February 3, 2023 at 12:10 PM, it was determined that the laboratory director failed to ensure that the laboratory retain the QA records for at least 2 years since November 2020. Refer to D 3039 (The laboratory failed to retain the Quality Assessment records (annual evaluations for the following systems: pre-analytic, analytic and post-analytic systems since November 2020).