

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 40D1031706	<b>(X3) Date Survey Completed</b> 02/07/2023
<b>Name of Provider or Supplier</b> Lab Centro Diagnostico Y Tratamiento Dr Cesar	<b>Street Address, City, State</b> Munoz Rivera Final, Juncos, 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>D5291</b>	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT 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> <p>This STANDARD is not met as evidenced by: Based on Quality Assessment (QA) activities records review and laboratory general supervisor interview on February 7, 2023 at 9:50 AM, it was determined that laboratory failed to evaluate and monitor the specimen identification and integrity in the General Laboratory system since February 2022. The findings include: a. On February 7, 2023 at 8:44 AM, the laboratory QA was requested. The QA showed that the laboratory has established to evaluate the patient's waiting time, at the reception area. This evaluation was included as part of the sample identification and integrity evaluations and must be performed twice a year. b. On February 7, 2023 at 8:50 AM the QA showed that the laboratory failed to evaluate and monitor the patient;s waiting time since February 2022. c. The laboratory general supervisor confirmed on February 7, 2023 at 9:50 AM that the laboratory failed to evaluate and monitor the time of patient waiting since February 2022.</p>
<b>D5791</b>	<p>ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c)</p> <p>(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.</p>

This STANDARD is not met as evidenced by:  
Based on Quality Assessment (QA) records and laboratory general supervisor interview on February 7, 2023 at 9:55 AM, it was determined that the laboratory failed to evaluate and monitor the requirement for analytic systems for Urinalysis since August 2022. The findings include: a. On February 7, 2023 at 9:00 AM, the laboratory QA record was requested. The QA showed that the laboratory established to evaluate the following analytical practices for urinalysis test: test procedures, accurate and reliable test system, reagents, materials, reagent storage conditions, system maintenance and function checks, control procedures, comparison of test results, corrective ations b. On Feburary 7 , 2023 at 9:10 AM the QA records showed that the laboratory did not evaluate the urinalysis analytical practices since August 2022. c. The laboratory general supervisor confirmed on February 7, 2023 at 9:55 AM that the laboratory failed to evaluate and monitor the requirement for analytic systems for Urinalysis since August 2022.

**D6094**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1445(e)(5)

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.

This STANDARD is not met as evidenced by:  
Based on Quality Assessment (QA) records reviewed and laboratory general supervisor interview on February 7, 2023 at 9:55 AM, it was determined that the laboratory director failed to ensure compliance with QA requirements. Refer to D5291, D5791.