

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  40D1003227	<b>(X3) Date Survey Completed</b>  05/12/2023
<b>Name of Provider or Supplier</b>  Cdt- Sala De Emergencia Sanos	<b>Street Address, City, State</b>  Calle Troche #2 Barrio Pueblo, Caguas, 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><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> <p>This STANDARD is not met as evidenced by: Based on Quality Assessment (QA) activities records review and laboratory director interview on May 12, 2023 at 10:00 AM, it was determined that laboratory failed to evaluate and monitor the patient confidentiality and complaint investigation in the General Laboratory system in the year 2022. The findings include: a. On May 12, 2023 at 9:31 AM, the laboratory QA was requested. The QA showed that the laboratory has established in the evaluation of patient confidentiality that what would be evaluated annually and the complaint investigation that what would be evaluated monthly. b. On May 12, 2023 at 9:40 AM the QA showed that the laboratory failed to evaluate and monitor the patient confidentiality in the year 2022 and failed to evaluate and monitor the complaint investigation since August 2022. c. The laboratory director confirmed on May 12, 2023 at 10:00 AM that the laboratory failed to evaluate and monitor the patient confidentiality and complaint investigation in the General Laboratory system in the year 2022.</p>
<b>D5891</b>	<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>

This STANDARD is not met as evidenced by:  
Based on Quality Assessment records review (QA) and laboratory director interview on May 12, 2023 at 10:00 AM, it was determined that the laboratory failed to follow the established Quality Assessment Program to monitor and evaluate the following requirements for postanalytic systems: accuracy of calculated data. The findings include: 1. On May 12, 2023 at 9:50 AM; the Quality Assessment records showed that the evaluations of the laboratory calculated data for hematology and chemistry must be performed twice a year. 2. The laboratory did not evaluate the accuracy of calculated data since February 22, 2022. 3. The laboratory director confirmed on May 12, 2023 at 10:00AM, that the laboratory did not evaluate the accuracy of calculated data since February 22, 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 Assesstment (QA) records reviewed and laboatroy director interview on May 12, 2023 at 10:00 AM; it was determined that the laboratory director failed to ensure the compliance with QA requirements. Refer to D5291 and D5891.