

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 40D0974756	<b>(X3) Date Survey Completed</b> 10/04/2019
<b>Name of Provider or Supplier</b> Lab Clinico Sunny Hills Inc	<b>Street Address, City, State</b> Avenida Santa Juanita B-6, Bayamon, 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>D5293</b>	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c)</p> <p>(b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities.</p> <p>This STANDARD is not met as evidenced by: Based on quality assessment (QA) procedures manual, complaint investigations records (years 2018 and 2019) review, laboratory director and general supervisor interview on October 04, 2019 at 12:10 PM, it was determined that the laboratory failed to follow written procedures to take corrective actions and to review of the effectiveness of this actions to prevent recurrence of the problems when the laboratory performed two complaint investigations( April 28, 2018 and July 18, 2019). The findings include: 1. The QA procedures manual for the complaint investigations policies require to take and document corrective actions to prevent recurrence of the problems. 2. On October 04, 2019 at 12:10 PM, from January 2018 to September 2019, the complaint investigations records showed that the laboratory did not take nor document corrective actions to prevent recurrence of the problems when it performed two complaint investigations: on April 28, 2018 ( identified in the pre-analytic system) and July 18, 2019 (identified in the post-analytic system). 3. The laboratory director and general supervisor confirmed on October 04, 2019 at 12:10 PM, that those complaint investigations did not include the documentation of the corrective actions nor the review of the effectiveness of this actions to prevent recurrence of the problems.</p>
<b>D6094</b>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</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.

This STANDARD is not met as evidenced by:

Based on QA procedures manual, complaint investigations records (years 2018 and 2019) review, laboratory director and general supervisor interview on October 04, 2019 at 12:10 PM, it was determined that the laboratory director failed to comply with the quality assessment (QA) requirements. Refer to D 5293 (The laboratory failed to follow written procedures to take corrective actions and to review of the effectiveness of this actions to prevent recurrence of the problems when the laboratory investigated two complaints ( April 28, 2018 and July 18, 2019).