

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0969568	(X3) Date Survey Completed 02/01/2019
Name of Provider or Supplier Laboratorio Clinico Visalmary	Street Address, City, State Car #638 Km 6 0 Bo Mira Flores, Arecibo, 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
D5791	<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> <p>This STANDARD is not met as evidenced by: Based on review of Quality Assessment (QA) records (January 2017 to February 1, 2019) and interview with the laboratory director on February 1, 2019 at 11:50 AM, it was determined that the laboratory did not evaluate the following QA criteria since January 2017: comparison of test results The findings include: 1. The QA evaluation records were reviewed from January 2017 to February 1, 2019. 2. During interview on February 1, 2019 at 11:50 AM the laboratory stated that the laboratory evaluated , each six months, the relationship of the White Blood Cells differentials results reported by the manual method and the Coulter HMX instrument. She also stated that the laboratory evaluated , by occurrence, the patient tests results for inconsistencies with patient information. 3. The evaluated QA records showed that the laboratory did not evaluate any aspect of the comparison test results since January 2017. 4. The laboratory director confirmed during the interview that they did not evaluated the criteria since year 2017.</p>
D6094	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p> <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.</p>

This STANDARD is not met as evidenced by:
Based on Quality Assessment (QA) records review and laboratory director interview on February 1, 2019 at 11:50 AM, it was determined that laboratory failed to ensure compliance with quality assessment (QA) requirements. The findings include: a. Quality Assessment records showed that the laboratory director did not evaluate the comparison of test results since January 2017. b. The director stated that , by omission, the requirement was not evaluated by her. Refer to D 5791.