

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0722887	(X3) Date Survey Completed 10/04/2018
Name of Provider or Supplier Laboratorio Clinico Stella Mikaela	Street Address, City, State Calle 2 , Bloque B-10, Urb Villa Real, Vega Baja, 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
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Pentra 60 C hematology system log records and interview with the laboratory director interview on October 4, 2018, it was found that the laboratory did not retain the instrument backgrounds checks results prior to August 30, 2018. The findings includes: a. The laboratory processed complete cell counts (CBC) by the Pentra 60 C instrument. b. The laboratory director was interview about the back ground checks tests results on October 4, 2018 at 10:45 AM. c. The laboratory director stated that she did not have the printouts but she can show the results on the instruments log. d. Review of the background results log showed that no result prior to August 30, 2018 was included in the log. The only results recorded were from August 30, 2018 to October 4, 2018. e. The laboratory processed around 900 CBC patient;s samples per year.</p>