

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D0959608	(X3) Date Survey Completed 09/20/2018
Name of Provider or Supplier Clara S P Chan Md Pc	Street Address, City, State 9801 Georgia Avenue #337, Silver Spring, MD	
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 instrument Quality Control (QC), Remedial Action Log and staff interview, the lab did not retain all quality control runs performed each day of patient testing. Findings include: 1. On 3/29/18; 6/18/18 and 7/31/18 lab quality control failed: on 7/31/18 instrument (Horiba MICROS 60) startup failed. 2. Review of the remedial action log on 3/29/18, the normal level QC was listed as out of range and repeated one time, however there was no evidence the lab saved the failed run. 3. Review of the remedial action log on 6/18/18, all three levels of QC were listed as out of range and repeated on 6/18 and 6/19, however there was no evidence the lab saved the failed run. 4. Review of the remedial action log on 7/31/18, all three levels of QC was listed as out of range and repeated, however there was no evidence the lab saved the failed run. 5. Review of the remedial action log on 7/31/18, the start-up was listed as failed, however there was no evidence the lab saved the failed run. 6. During interview with the testing individual at approximately 3:30pm, there was an admission that the QC and start-failures were trouble-shot and corrected, however the lab only kept records of the acceptable qc and did not maintain the unacceptable qc and start-up records.</p>