

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D2119300	(X3) Date Survey Completed 12/11/2018
Name of Provider or Supplier Louisiana Coagulation	Street Address, City, State 8721 Oak Street, New Orleans, LA	
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: A Revisit Survey was performed at Louisiana Coagulation, CLIA ID # 19D2119300 on December 11, 2018. Based on observation, record review and interview with personnel, the laboratory failed to retain manufacturer package inserts for Homocysteine testing. Findings: 1. In interview on December 11, 2018 at 1:20 pm, Personnel 2 stated the laboratory began patient testing for Homocysteine on August 23, 2018. 2. Observation by surveyor on December 11, 2018 revealed the laboratory utilizes the Diazyme Smart 700/340 analyzer for Homocysteine testing. 4. Review of the laboratory's records for Homocysteine testing revealed the laboratory did not have an instrument manual or manufacturer package insert that specified sample and instrument requirements. 5. In interview on December 11, 2018 at 1:31 pm, Personnel 2 stated the Diazyme instrument only came with test kit information, not a manual.</p>