

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D0367764	(X3) Date Survey Completed 11/18/2020
Name of Provider or Supplier Medical Group Practice Pc	Street Address, City, State 9460 Middlebelt Road, Livonia, MI	
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 observation and interview with Testing Personnel #1 (TP1), the laboratory failed to retain quality control documentation when controls failed for 2 (November 2018 to November 2020) of 2 years reviewed. Findings include: 1. On 11/18/20 at 10:17 am the surveyor observed TP1 performing quality control testing on the Abbott Cell-Dyn Emerald hematology analyzer. TP1 reran level 1 twice and deleted the electronic files of the failed quality control runs. When the runs were printed, TP1 took the failed runs and put them in a separate pile from the successful quality control runs. 2. An interview on 11/18/20 at 10:20 am with TP1 revealed when quality control fails, the laboratory deletes the electronic file of the run and does not retain the printed copy as part of the laboratory's analytic system records.</p>