

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D0893112	(X3) Date Survey Completed 04/08/2024
Name of Provider or Supplier Patient First -Lutherville	Street Address, City, State 10755 Falls Road Suite 160, Lutherville, 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 laboratory record review and interview with the technical consultant (TC), the laboratory failed to retain all patient test records for at least 2 years. Findings: 1. The laboratory performs chemistry testing using an Abbott i-STAT blood analyzer. Patient results are written on the "i-STAT Chemistry Log" and the print out from each patient is attached to the back of the log with cellophane tape. Adhering cellophane tape to thermal paper print outs can cause the printing to fade or disappear. 2. A review of "i-STAT Chemistry Logs" from November 2022 showed that the patient's medical record number was illegible or missing on the thermal paper print out for 21 of 119 patients run between 11/05/2022 and 11/21/2022. 3. Patient chemistry results were illegible on the thermal paper print out for one of 20 patients tested on 11/21/2022 and three of 16 print outs were completely illegible for patients tested on 11/12/2022 because the thermal paper had turned very dark. 4. During an interview on 04/08/2024 at 12:30 PM, the TC confirmed that the laboratory failed to retain all patient test records for at least 2 years.</p>