Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D0893112	(X3) Date Survey Completed 02/05/2021
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	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) 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. This STANDARD is not met as evidenced by: Based on laboratory record review and interview with the technical consultant (TC), the laboratory did not retain all analytic systems records for at least 2 years. Findings: 1. The following documents were requested for review as part of a remote survey for the time periods March through June, 2019, and August through November, 2020: calibration and quality control (QC) records for all moderate complexity tests being performed, and temperature and instrument maintenance logs. 2. During a phone conversation on 12/10/2020 at 5:25 PM, the TC stated that the laboratory supervisor had "shredded most of the records from 2019 by accident." The laboratory was unable to provide hematology analyzer maintenance logs, temperature logs, and weekly serum pregnancy test QC for March through June, 2019; and 3. The TC stated in an email on 1/3/2021 that "no calibration records" (were available for the hematology analyzer) "prior to January 2019. The last page of the attachment for the calibration performed on 1.7.2019 shows the calibration history but the documentation was unable to be located." Hematology analyzer calibration record review confirmed this statement. 4. During a phone interview on 1/22/2021 at 3:15 PM, the TC confirmed that the laboratory did not retain all analytic system records for at least 2 years.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform

	test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on record review and interview with the technical consultant (TC), the laboratory director (LD) did not ensure that the laboratory had documentation that all testing personnel had the appropriate education to perform laboratory testing. Findings: 1. The laboratory currently has 6 testing personnel listed on the "Laboratory Personnel Report (CMS-209)." A review of the testing personnel's credentials showed that 1 of 6 testing personnel had a "Bachelor of Science in Medical Technology" from a university in the Philippines. 2. Record review showed that there was no documentation that an evaluation of their credentials determining equivalency of foreign to United States education had been performed. 2. During the phone exit interview on 2/5/2021 at 3:15 PM, the TC confirmed that the LD did not ensure that all testing personnel had the appropriate education to perform laboratory testing.