Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D2070705	12/06/2023
Name of Provider or Supplier	**Street Address, City, State**	
Patient First - Easton	2450 Butler Street, Easton, PA	

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
D3009	FACILITIES CFR(s): 493.1101(c) The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements. This STANDARD is not met as evidenced by: Based on record review and interview with technical consultant (TC) #1, the laboratory failed to ensure that the State of Pennsylvania (PA) regulations were met regarding having a supervisor on site during all normal scheduled working hours in which tests were performed from 01/19/2022 through the day of the survey. Findings include: 1. The PA regulation (5.23(b)(1) states: "A general supervisor who meets all the requirements of subsection (a)(1), (2) or (3) and is on the laboratory premises during all normal scheduled working hours in which tests are being performed." 2. Review of the application for Exception to Section 5.22 (f) form signed by the laboratory director (LD) on 04/19/2022 states: " the laboratory director will appoint a qualified general supervisor for each laboratory who will be on-site to oversee laboratory operations during all hours in which testing is being performed and who will review quality control records on a weekly basis". 3. The laboratory's Quality Assurance: Laboratory Supervisor Job Description police (page 5) states, " Employee must be a High School graduate (or equivalent) and must meet one of the following requirements: - Incumbent must hold a Bachelor's Degree in medical technology or chemical, physical, or biological science and six years experience. - Incumbent must hold a doctoral degree from an accredited institution and have acceptable lab experience. 4. On the day of the survey, 12/06/2023 at 09:20 am, review of the laboratory personnel report (PA State) and personnel credentials revealed that the laboratory failed to ensure that the PA regulations were met regarding having a qualified supervisor on site during all hours of patient testing and to ensure laboratory supervisor qualifications were met per the laboratory's procedure from 01/19/2022 to 12/06/2023. 5. TC#1 confirmed the findings above on 12/06/2023 at 01:30 pm.

D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on review of the laboratory's quality control (QC) records and interview with technical consultant (TC) #1, the laboratory failed to provide documentation of the corrective actions taken for QC results that failed to meet the laboratory's established acceptable criteria for hematology testing performed from 10/01/2023 to 10/31/2023. Findings Included: 1. On the day of survey, 12/06/2023 at 11:48 am, review of the laboratory's QC records revealed that the following 1 of 31 days of QC results reviewed for hematology testing performed on the Horiba Pentra 60 C+ from 10/01 /2023 to 10/31/2023 failed to meet the laboratory's established acceptable criteria: - 10 /29/2023: - White Blood Cell Low Level AM result: 2.42, acceptable range: (2.60-3.40) - Neutrophil # Low Level AM result: 1.12, acceptable range: (1.15-1.85) 2. The laboratory's Quality Assessment-Overview policy (page 8) states, "Any control result that is out-of-range is circled on the QC log and the corrective action taken is documented on the Hematology Control/Corrective Action form." 3. The laboratory could not provide documentation of the corrective actions taken for QC performed on the Horiba Pentra 60 C+ that did not meet the laboratory's established acceptable criteria on 10/29/2023. 4. TC #1 confirmed the findings above on 12/06/2023 at 01:50 pm.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on lack of documentation, review of patient reports, and interview with technical consultant (TC) #1, the TC failed to assess the competency of 2 of 7 testing personnel (TP) that performed microbiology, clinical chemistry, hematology and urinalysis testing in 2022 and 2023. Findings include: 1. On the day of survey, 12/06 /2023 at 12:20 pm, review of the laboratory's patient reports revealed that TP #6 performed a serum pregnancy test on 10/21/2022 and TP #7 performed microbiology, clinical chemistry, hematology and urinalysis testing on 10/25/2023. 2. The laboratory could not provide the 2022 competency records for TP #6 (serum pregnancy) and the 2023 competency records for TP #7 (hematology, chemistry, microbiology, and urinalysis). 3.TC#1 confirmed the findings above on 12/06/2023 at 01:50 pm.
D6051	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(v)

	The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. This STANDARD is not met as evidenced by: Based on review of competency assesment (CA) records and interview with technical consultant (TC) #1, the TC failed to evaluate the competency of 1 of 7 testing personnel (TP) through internal blind testing samples or external proficiency testing (PT) samples for chemistry testing in 2023. Findings Include: 1. On the day of survey, 12/06/2023 at 09:41 am, review of CA records revealed the TC failed to evaluate and document the test performance of 1 of 7 TP (CMS 209 TP #5) through internal blind sampling, external PT or previously analyzed samples for the following: - 2023 Semi annual competency assessment performed 03/29/2023: - Abbot i-STAT Chem 8+ cartridges - Serum Human Chorionic Gonadotropin (hcG) 2. The laboratory performed 9,000 chemistry examinations in 2023 (CMS-116 annual volume). 3. TC #1 confirmed the findings above on 12/06/2023 at 1:50 p.m.