Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D2023268	08/22/2023
Name of Provider or Supplier	**Street Address, City, State**	
Patient First-East York	2960 East Market Street, York, 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 #1 (TC), 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 06/17/2021 through the day of 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. On the day of the survey, 08/22/2023 at 01:45 pm, review of the laboratory personnel report (PA State), personnel credentials and personnel schedules revealed the laboratory failed to ensure that the PA regulations were met regarding having a qualified supervisor on site during all normal scheduled working hours in which tests were performed for the following days in November 2021, August 2022, and February 2023: - 13 of 30 days in November 2021 - 16 of 31 days in August 2022 - 22 of 28 days in February of 2023 3. TC#1 confirmed the above findings on 08/22/2023 at 02: 45 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, tour of the laboratory, and interview with technical consultant #1 (TC), 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 07/02/2023 to 07/15/2023. Findings Included: 1. On the day of survey, 08/22 /2023 at 11:52 am, review of the laboratory's QC records revealed that the following 1 of 14 days of QC results reviewed for hematology testing performed on the Horiba Pentra 60 C+ from 07/02/2023 to 07/15/2023 failed to meet the laboratory's established acceptable criteria: - 07/09/2023: - Red blood cell Level 3 result: 4.92, acceptable range: (4.98- 5.48) - Hemoglobin Level 3 result: 16.3, acceptable range: (16.4-17.6) - Hematocrit Level 3 result: 45.9, acceptable range: (46.1-51.1) 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 07/09/2023. 4. TC #1 confirmed the findings above on 08/22/2023 at 02:45 pm.
D6035	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 (a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be

	acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service. This STANDARD is not met as evidenced by: Based on review of personnel qualification records, quality control records, and interview with technical consultant #1 (TC), the laboratory failed to ensure that 1 of 1 laboratory staff who performed the responsibilities of a technical consultant (TC) from 6/17/2021 to the date of survey met the required TC qualifications under C.F.R 493.1411. Findings include: 1. Review of QC records and interview with TC #1, on 08 /22/2023 at 12:54 pm, revealed that testing personnel #2 (TP) performed the duties of a TC listed under C.F.R. 493.1413 from 06/17/2021 to 08/22/2023. 2. Review of the CMS 209 personnel form, signed by the laboratory director (LD) on 08/09/2023, did not list TP # 2 as a TC. 3. Further review of personnel credentials provided on the date of suvey, 08/22/2023 at 10:00 am, revealed TP #2 has a high school diploma with U.S military medical laboratory training, which does not meet the minimal educational qualifications (493.1411) to perform technical consultant responsibilities for moderate complexity testing. 4. TC #1 confirmed the findings above on 08/22/2023 at 02:45 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 review of competency assessment records, personnel schedules, and interview with technical consultant #1 (TC), the TC failed to assess the competency of 6 of 12 testing personnel (TP) that performed microbiology, clinical chemistry, hematology and urinalysis testing from 11/01/2021 to the day of survey. Findings include: 1. On the day of survey, 08/22/2023 at 01:20 pm, review of the laboratory's competency assesment records, and personnel schedules revealed that the TC did not assess the competency of 5 of 12 TP (CMS 209 TP # 8, 9, 10, 11, and 12) that performed microbiology, clinical chemistry, hematology and urinalysis testing from 11 /1/2021 to 08/22/2023. 2. The following required procedures were not documented for 1 of 12 TP (CMS 209 TP # 4) that performed urine microscopic examinations from 01 /01/2022 to 01/26/2023: - Missing point #1: Direct observation of routine patient test performance - Missing point #2: Monitoring the recording and reporting of test results - Missing point # 3: Review of intermediate test results, quality control, proficiency testing, and preventative maintenance. - Missing point #4: Direct observation of performance of instrument maintenance and function checks. 3.TC#1 confirmed the findings above on 08/22/2023 at 02:45 pm.