| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 39D2023268 | 07/09/2025 |
| **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 |
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| **D0000** | An onsite recertification survey was conducted by the Pennsylvania Department of Health at the Patient First-East York laboratory on 07/09/2025. The laboratory was found out of compliance with the following conditions: 42 CFR. 493.1409 Technical Consultant-Moderate Complexity. |
| **D5209** | PERSONNEL COMPETENCY ASSESSMENT POLICIES<br>CFR(s): 493.1235<br><br>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.<br><br>This STANDARD is not met as evidenced by:<br>Based on lack of documentation and interview with Technical Consultant (TC) #1, the laboratory failed to establish a competency assessment procedure to assess 2 of 13 testing personnel (TP) for their supervisory responsibilities performed from 8/22/2023 to 7/9/2025. Findings Include: 1. On the day of survey, 7/9/2025 at 12:30 pm, the laboratory failed to provide a competency assessment procedure to assess the competency of TP #3, and #9 (CMS 209 form dated 6/3/2025) for their supervisory responsibilities performed in the laboratory from 8/22/2023 to 7/9/2025. 2. The laboratory failed to provide CA records for TP#3 and #9 for their supervisory responsibilities performed from 8/22/2023 to 7/9/2025. 3. The Technical Consultant (TC)#1 confirmed the findings above on 7/9/2025 at 12:45 pm. |
| **D5891** | POSTANALYTIC SYSTEMS QUALITY ASSESSMENT<br>CFR(s): 493.1299(a)<br><br>(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291. |

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| | This STANDARD is not met as evidenced by:<br>Based on record review and interview with Technical Consultant (TC) #1, the laboratory failed to follow established written polices for an ongoing mechanism to monitor, assess, and correct problems identified for postanlytical systems specified in 493.1291(k) when errors were found for 1 of 1 patient test report reviewed from 8/22/2023 to 7/9/2025. Findings include: 1. On the day of survey, 7/9/2025 at 12:30 pm, review of the Quality Assurance: Deficiency/Corrective Action Log Sheet revealed the red blood cell (RBC) results documented on the urinalysis worksheet were 3-5 and the RBC results documented in the medical record (MR) were 1-2 for microscopic urinalysis test results performed on 05/28/2025 for MR #32231.1. 2. The Deficiency/Corrective Action Log completed by the laboratory supervisor on 6/6/2025 stated "On 6/2/2025, the nature of the Corrective Action was Clerical error on log of 3-5 RBCs. The employee made clerical error correction on log with error correction on back of log." 3. The laboratory's Quality Assessment-Overview policy stated the following: - Page 15 of 16: "Verifying Manual Result Entries: Lab Supervisors will compare written logs to the manual entries in the Medical Record by reviewing at least 10% of the results on each log sheet weekly. If an error is found, the corrected result is documented in the Medical Record as outlined in the procedure: Corrections Made in the Medical Record. " - Page 14 of 16: "The procedure for making a correction of the patient name, medical record or results on a Patient First log sheet is as follows: 1. A line is drawn through the error and initialed. 2. A corrected entry may be written on the same line if there is space. Otherwise the result is written on a separate line. 3. An explanation for the error is made on the reverse of the log sheet." 4. The laboratory failed to provide documentation for the corrective action taken when errors were found when comparing written log results to manual entries in the MR for 1 of 1 patient report (MR#32231.1) for a microscopic urinalysis examination performed 5/28/2025. 5. TC#1 confirmed the findings above on 7/9/2025 at 12:45 pm. |
| **D6004** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(a)(b)<br><br>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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of quality assurance (QA), quality control (QC), and competency assessment (CA) records, and interview with Technical Consultant (TC) #1, the laboratory director (LD) failed to provide written documentation of the responsibilities delegated to 2 of 13 Testing Personnel (TP) that performed the duties of a technical consultant from 8/22/2023 to 7/9/2025. Findings Include: 1. On the day of survey, 7/9/2025 at 11:00 am, review of QA,QC, and CA records revealed 2 of 13 TP (CMS 209 TP#3 and #9) performed the duties of a TC from 08/22/2023 to 7/9/2023. 2. The laboratory failed to provide written documentation of the TC |

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| | responsibilities delegated to TP #3 and #9 by the LD. 3. The TC#1 confirmed the findings above on 7/9/2025 at 12:30 pm. |
| **D6033** | TECHNICAL CONSULTANT-MODERATE COMPLEXITY<br>CFR(s): 493.1409<br><br>The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.<br><br>This CONDITION is not met as evidenced by:<br>Based on review of personnel qualification records and interview with Technical Consultant (TC) #1, the laboratory failed to ensure 1 of 1 TP (CMS 209 TP#1 dated 6 /3/2025) performing the duties of a technical consultant met the qualification requirements (493.1411) for moderate complexity testing from 8/22/2023 to 7/9/2025. Refer to D6035. |
| **D6035** | TECHNICAL CONSULTANT QUALIFICATIONS<br>CFR(s): 493.1411<br><br>(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 (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 1 year of laboratory training or experience, or both, in nonwaived 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)(A) Hold an earned doctoral or master's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(3)(i)(B) Meet either requirements in 493.1405(b)(3)(i)(B) or (b)(4)(i)(B) or (C); AND (b)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i)(A) Have earned a bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(4)(i)(B) Meet 493.1405(b)(5)(i)(B); and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(5)(i) Have earned an associate degree in medical laboratory technology, medical laboratory science, or clinical laboratory science; and (b)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. (b)(6) For blood gas analysis, the individual must- (b)(6)(i) Be qualified under paragraph (b)(1), (2), (3) or (4) of this section; or (b)(6)(ii)(A) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; and (b)(6)(ii)(B) Have at |

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| | least 2 years of laboratory training or experience, or both, in blood gas analysis; or (b) (7) Notwithstanding any other provision of this section, an individual is considered qualified as a technical consultant under this section if they were qualified and serving as a technical consultant for moderate complexity testing in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and interview with technical consultant (TC) #1, the laboratory failed to ensure that 1 of 1 Testing Personnel (TP) who performed the responsibilities of a technical consultant (TC) from 8/22/2023 to the date of survey met the required TC qualifications under C.F.R 493.1411. Findings include: 1.On the day of the survey, 7/9/2025 at 1:00 pm, review of QC records and Patient First's Lab Supervisor Checklist (February 2025) revealed 1 of 1 TP (Form CMS 209, TP #1) performed the duties of a TC listed under C.F.R. 493.1413 from 8/22/2023 to 7/9 /2025. The Form CMS-209, signed by the laboratory director (LD) on 6/3/2025, did not list TP # 1 as a TC. 2. The laboratory's Quality Assurance: Laboratory Supervisor Job Description stated, " Qualifications and and Technical Knowledge: D. Employee must be a High School graduate (or equivalent) and must meet one of the following requirements: 1. Incumbent must hold a Bachelor's Degree in medical technology or chemical, physical, or biological science and six years experience. 2. Incumbent must hold a doctoral degree from and accredited institution and have acceptable lab experience." 3. Further review of personnel credentials on the date of survey, 7/9/2025 at 10:00 am, revealed TP #1 has a high school diploma with U.S military medical laboratory training. 4. TC #1 confirmed on 7/9/2025 at 12:45 pm that TP#1 did not meet the minimum qualifications stated in the laboratory's written job description and under C.F.R 493.1411 to perform the duties of a TC. * Repeat Deficiency |