

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  39D2071197	<b>(X3) Date Survey Completed</b>  12/13/2023
<b>Name of Provider or Supplier</b>  Patient First - Bethlehem	<b>Street Address, City, State</b>  2310 Schoenersville Road, Bethlehem, PA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2009</b>	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on review of the AAB-Medical Laboratory Evaluation (AAB-MLE) proficiency testing (PT) records and interview with Technical Consultant (TC)#1, the testing personnel (TP) failed to sign 1 of 9 AAB-MLE procedures on the attestation statement document for the Provider Performed Microscopy (PPM) testing performed in 2023. Findings Include: 1. On the day of the survey, 12/13/2023 at 10:00 am, review of the AAB-MLE PT attestation statement records for event 2 in 2023 revealed that the TP who performed the PPM portion of proficiency testing did not sign the document. 2. TC#1 confirmed the findings above on 12/13/2023 around 12:45 pm.</p>
<b>D3009</b>	<p>FACILITIES CFR(s): 493.1101(c)</p> <p>The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements.</p> <p>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 01/20/2022 through the day of the survey. Findings include: 1. The PA regulation (5.23(b)(1) states: "A general supervisor who meets all</p>

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 survey 12/13/2023 at 09:05 am, review of the Clinical Laboratory Improvement Amendments (CLIA) Application for certification (CMS 116) form revealed the laboratory director (LD) serves as director of 2 more facilities: Patient First Allentown and Patient first Easton. 3. Review of the laboratory personnel Report (Pennsylvania State) revealed that the laboratory director is the only general supervisor for this facility. 4. The laboratory's Quality Assurance: Laboratory Supervisor Job Description policy (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. 5. 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 01/20/2022 to 12/06/2023. 6. TC#1 confirmed the findings above on 12/13/2023 at 12:40 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 and interview with technical consultant (TC) #1, the TC failed to assess the competency of 5 of 8 testing personnel (TP) that performed microbiology, clinical chemistry, hematology and urinalysis testing from 01/20/2022 to 12/13/2023. Findings include: 1. On the day of survey, 12/12/2023 at 09:21 am, the laboratory could not provide competency assesment records performed on site for 5 of 8 TP (cms209 personnel #2, #8, #9, #10 and #11) who performed microbiology, clinical chemistry, hematology and urinalysis testing from 01/20/2022 to 12/13/2023. 2. TC#1 confirmed the findings above on 12/13/2023 around 12:45 pm.