

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  39D2172419	<b>(X3) Date Survey Completed</b>  10/11/2023
<b>Name of Provider or Supplier</b>  Patient First - Langhorne	<b>Street Address, City, State</b>  100 Lincoln Highway, Fairless Hills, 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>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 a qualified general supervisor was on -site during all normal scheduled working hours in which tests were performed from 10/26/21 through the day of survey as required by the PA state regulations. 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, 10/11/2023 at 01:45pm, a review of the laboratory personnel report revealed that a qualified general supervisor was not on - site during all hours of patient testing from 10/26/2021 to 10/11/2023 as required by the PA state regulation. 3. The hours of operation for this facility are Monday to Sunday 08:00 am to 08:00 pm (CMS 116). 4. TC#1 confirmed during an interview at 01:45 pm on 10/11/2023 that the laboratory director oversees another Patient First laboratory. A qualified general supervisor was not on - site during all hours of testing whenever the Director was not physically on - site from 10/26/21 - 10/11/2023.</p>
<b>D5891</b>	<p>POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a)</p> <p>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.</p>

This STANDARD is not met as evidenced by:  
Based on review of patient records, and interview with technical consultant (TC)#1, the laboratory failed to establish and follow written policies for an ongoing mechanism to monitor, assess and when indicated, correct problems identified in the postanalytic systems specified in 493.1291 from 10/26/2021 to 10/11/2023. Findings include: 1. On the date of the survey, 10/11/2023 at 12:00 pm, review of patient test reports and instrument printouts revealed discrepant results for 1 of 2 patients reviewed for the following hematology testing performed on the Horiba Pentra 60+ and the results reported from the electronic medical record (EMR) on 09/26/2023: - White blood cell count: - EMR result: 8.3 - Horiba Pentra 60+ instrument printout: 8.2  
2. The laboratory could not provide a procedure or documentation of the ongoing mechanism used to monitor and assess the transmission of accurate patient results between the Horiba Pentra 60+ hematology instrument and the EMR. 3. During an interview with TC#1 on 10/11/2023 at 01:45 pm, TC#1 could not explain the discrepant results between the instrument and the EMR.

**D6047**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(8)(i)

The procedures for evaluation of the competency of the staff must include, but are not limited to direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing.

This STANDARD is not met as evidenced by:  
Based on review of competency assessment records, the Quality Assessment-Overview procedure, and interview with technical consultant (TC)#1, the TC failed to perform direct observation of routine patient test performance, including handling, processing, and testing of patient specimens for 18 of 18 testing personnel (TP) that performed parasitology, mycology and hematology testing from 10/26/2021 to the date of the survey. Findings include: 1. The laboratory's Quality Assessment-Overview policy (page 3) states, "Observation of the tech's performance of laboratory testing (Observe-A-Tech) is performed yearly. Additional tech observations are performed on newly hired techs after 6 months and 12 months of employment." 2. On the day of the survey, 10/11/2023 at 01:45 pm, interview with TC #1 revealed that the laboratory did not perform direct observations of routine patient test performance, including handling, processing, and testing of patient specimens for 18 of 18 TP that performed pinworm, Potassium Hydroxide (KOH), wet mounts and Fecal Leukocyte microscopic examinations from 10/26/2021 to 10/11/2023. 3. TC #1 confirmed on 10/11/2023 at 01:45 pm, that a written test was provided to all TP electronically in lieu of performing direct observations.

**D6054**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:  
Based on record review and interview with consultant (TC)#1, the technical

consultant failed to evaluate the competency assessment for 10 of 14 testing personnel (TP) that performed moderate complexity testing in microbiology, clinical chemistry, hematology and urinalysis in 2021 and 2022. Findings include: 1. On the day of survey 10/11/2023 at 01:20 pm, review of the CMS 209 and competency assessment records revealed that the Technical Consultant did not evaluate the annual competency assessment for 10 of 14 TP (CMS 209 personnel #9, #10, #11, #12, #13, #14, #15, #16, #17, and #18) that performed moderate complexity testing in microbiology, clinical chemistry, hematology and microscopic urinalysis in 2021 and 2022. 2. TC#1 confirmed the findings above on 10/11/2023 around 01:45 pm.