

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 01D1034919	<b>(X3) Date Survey Completed</b> 03/28/2018
<b>Name of Provider or Supplier</b> Physical Express - Millbrook	<b>Street Address, City, State</b> 4081 Al Hwy 14, Millbrook, AL	
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>D2007</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on a review of the 2016 American Association of Bioanalysts (AAB) and 2017 American Proficiency Institute (API) proficiency testing records, personnel records, and an interview with the office manager and Testing Personnel # 1, the laboratory failed to ensure proficiency testing samples were rotated between all testing personnel who routinely perform moderate complexity testing. This was noted on four of six surveys reviewed. The findings include: 1. A review of the attestation statements revealed, a previous employee (listed as Testing Personnel #5 on the previous survey) performed all the proficiency testing from the 3rd event of 2016 to the 3rd event of 2017. 2. A review of the personnel files revealed Testing Personnel #1 (TP #1) and TP #2 were full time, and had been previously qualified to perform moderate complexity testing since the last survey conducted on 9/10/15. 3. During an interview conducted on 3/28/2018 at 4:30 PM, the office manager was asked why the previous employee performed the proficiency testing from the third event of 2016 to the third event of 2017. The office manager and TP #1 stated that whomever came in to work first performed the proficiency testing. Thus the above noted finding were confirmed.</p>
<b>D6029</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(11)</p> <p>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</p>

and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:

Based on a review of the personnel records and an interview with the office manager and Testing Personnel #1, the Laboratory Director failed to ensure the competency for two of two moderate-complexity testing personnel was assessed annually by himself or a designee qualified for that responsibility. The findings include: 1. A review of the personnel files revealed, Testing Personnel #1 (TP#1) had annual competency evaluations performed on 11/22/16 and 5/18/17 and TP #2 had annual competency evaluations performed 11/21/16 and 5/18/17, however both were signed by a previous office manager. 2. In an interview conducted on 3/28/2018 at 4:30 PM, the surveyor asked if the previous office manager had been designated by the Laboratory Director and had the minimum educational requirements to perform this responsibility. The office manager reviewed the training records with the surveyor and confirmed that the previous office manager was not qualified to sign annual competency assessment records.

**D6033**

**TECHNICAL CONSULTANT-MODERATE COMPEXITY**  
CFR(s): 493.1409

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.

This CONDITION is not met as evidenced by:

Based on a review of the CMS-209 and an interview with the office manager and Testing Personnel #1 (TP #1), the laboratory failed to specify a qualified Technical Consultant to provide technical oversight for the laboratory. The findings include: 1. During a review of the personnel listed on the CMS-Form 209 with the office manager on 3/28/2018 at 2:00 PM, the surveyor noted that the laboratory failed to specify a Technical Consultant (TC). The surveyor then asked who was the laboratory's TC. The office manager then asked what duties a TC performed for a laboratory. The surveyor then reviewed with the office manager the responsibilities and educational requirements for a TC in the CLIA regulations. 2. During the exit interview with the office manager and TP #1 on 3/28/2018 at 4:30 PM, the office manager listed a TC, however the facility was unable to provide educational credentials for the TC during the survey. The office manager asked if she could forward the education credentials to the CLIA office by Wednesday, and the surveyor agreed stating the documentation must be received by Friday 3/30/2018. However, no additional information has been sent to the surveyor as of the close of business on 3/30/2018. Jeremy Westry, BS, MT (ASCP) Licensure and Certification Surveyor