

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D2063455	(X3) Date Survey Completed 03/29/2018
Name of Provider or Supplier Physical Express - Holtville	Street Address, City, State 4412 Hogan Road, Deatsville, AL	
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
D6029	<p>LABORATORY DIRECTOR RESPONSIBILITIES 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 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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the personnel records and an interview with Testing Personnel #1 (TP #1), the Laboratory Director failed to ensure the competency for one of one testing personnel was assessed by himself or a designee qualified for that responsibility. 1. A review of the personnel files revealed, TP #1 had annual competency evaluations performed on 11/22/16 and 5/17/17, However both were signed by a previous office manager. 2. In an interview conducted on 3/29/2018 at 12:00 PM, the surveyor asked why would the previous office manager signed the annual competency evaluations. TP #1 explained the previous office manager signed the competency evaluations because he was in charge of the laboratory. The surveyor explained the previous office manager did not meet the qualifications per the CLIA guidelines to perform this duty.</p>
D6033	<p>TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409</p> <p>The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in</p>

accordance with 493.1413 of this subpart.

This CONDITION is not met as evidenced by:

Based on a review of the CMS-209 form and an interview with 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 an initial tour of the laboratory on 3/29/2018 at 8:45 AM, the surveyor and TP #1 reviewed the CMS-209 form which listed a new Technical Consultant, however the facility was unable to provide educational credentials for the Technical Consultant during the survey. 2. In an interview on 3/29/2018 at 12:00 PM, TP #1 stated that the office manager would send the educational credentials to the CLIA office by Wednesday 3/28/2018.

However, no additional information was received by the CLIA office by the close of business on that date. Jeremy Westry, BS, MT (ASCP) Licensure and Certification Surveyor