

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 39D0665612	<b>(X3) Date Survey Completed</b> 04/12/2018
<b>Name of Provider or Supplier</b> Lower Bucks Hospital Resp Therapy	<b>Street Address, City, State</b> 501 Bath Road, Bristol, 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>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> CFR(s): 493.1235</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory personnel competency assessment (CA) records and interview with the Testing Personnel #1 (TP#1) and Technical Consultant #2 (TC #2), the technical consultant (Laboratory Director) failed to have a written CA procedure to assess the regulatory responsibilities of 1 of 2 (TC #2) from 2016 through the date of survey. Findings Include: 1. On the date of survey, 04/12/2018, after review of testing personal competency assessment records, the surveyor observed that no CA was performed for TC #2 from 2016 to the date of inspection. 2. The TP #1 and TC #2 confirmed the finding above at 12:15 pm.</p>
<b>D6051</b>	<p><b>TECHNICAL CONSULTANT RESPONSIBILITIES</b> CFR(s): 493.1413(b)(8)(v)</p> <p>The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples.</p> <p>This STANDARD is not met as evidenced by: Based on, the review of competency assessment records, American Proficiency Institute (API) proficiency testing (PT) records and interview with testing personnel #1 (TP#1) and technical consultant #2 (TC #2), the Technical Consultant ( Laboratory Director) failed to assess the competency of 6 of 17 TP through internal blind testing</p>

samples or external PT samples for Blood Gases in 2016 and 2017. Findings Include:  
1. On the day of survey, 04/12/2018, the competency records reviewed showed that 6 of 17 TP performed Blood Gases PT events (1-3) in 2016 and 2017. 2. 11 of 17 TP who performed Blood Gases patient testing in 2016 and 2017 did not perform nor were assessed through internal blind testing samples. 3. TP#1 and TC #2 confirmed the findings above on 04/13/2018 around 9:30 am.