

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0669942	(X3) Date Survey Completed 11/20/2018
Name of Provider or Supplier Alley Medical Center Laboratory	Street Address, City, State 301 West 3rd Street, Berwick, PA	
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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES 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's personnel evaluation procedure and interview with the testing personnel (TP) #1, the laboratory failed to establish a complete procedure on how to assess testing personnel and consultant competency from 04/19/2017 to the time of survey. Findings include: 1. On the day of survey, 11/20/2018, the laboratory failed to provide a complete written policy that reviews how to assess the competency of laboratory testing personnel and the competency of consultant's regulatory responsibilities. 2. The TP #1 confirmed the findings at the time of survey, 11/20/2018 around 10:00 am.</p>
D6051	<p>TECHNICAL CONSULTANT RESPONSIBILITIES 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 personnel competency assessment records, American Proficiency Institute (API) proficiency testing (PT) records and interview with the technical consultant #2, the Technical Consultant failed to assess the competency of 3 of 4 testing personnel (TP) through internal blind testing samples or external PT</p>

samples for chemistry and hematology testing in 2017. Findings Include: 1. On the day of survey, 11/20/2018, review of personnel competency assessments and API attestation forms revealed the laboratory did not assess the test performance of 3 of 4 TP through internal blind testing samples or external PT samples in 2017 for Chemistry on the Alfa Wasserman Ace Alera, Tosoh A1A 360 and Hematology on the Sysmex KX 21. 2. TP #1 was the only personnel performing in 2017 API PT evaluations. 3. TP#1 confirmed the findings above on 10/20/2018 around 10:30 am.