

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0184808	(X3) Date Survey Completed 09/17/2020
Name of Provider or Supplier Penn Highlands Tyrone	Street Address, City, State 187 Hospital Drive, Tyrone, 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 competency assessment records and interview with Technical Supervisor (TC), the laboratory failed to establish written policies and procedures to assess competency for 1 of 1 Technical Consultant, 1 of 2 Technical Supervisors, and 4 of 5 General Supervisors from (07/18/2018) through the date of the survey (09/16/2020). Findings include: 1. At the time of the survey, the laboratory could not provide written policies and procedures to assess Technical Consultant, Technical Supervisor, & General Supervisor competency. 2. A review of the competency assessment records revealed there was no documentation of supervisor competency assessment from (07/18/2018) through the date of the survey (09/16/2020). 3. During the survey at (10:30 09/16/2020), the Technical Supervisor confirmed, the above findings.</p>
D5211	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based a review of proficiency testing records and interview with the Technical Consultant on the date of the survey (06/16/2020), the Laboratory failed to ensure</p>

review and evaluation of the results obtained on proficiency testing for 2 of 10 American Proficiency Institute (API) 2019 2nd event analytes. Findings include: 1. A review of API proficiency test records revealed a score of 80%, of 1 of 5 for Fibrinogen (COA-06) 2019 2ND event and a score of 80%, of 1 of 5 for Eosinophils (Hem-5C2) 2019 2ND event. 2. The laboratory could not provide documentation of evaluation & review performed on the 2019 API Fibrinogen and Eosinophil 2nd event. 3. During the survey (10:30 06/16/2020), the Technical Supervisor confirmed the above findings.