

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0694814	(X3) Date Survey Completed 03/20/2023
Name of Provider or Supplier Pennsylvania Automated Services	Street Address, City, State 620 Lowry Ave, Jeannette, 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 the Technical Consultant (TC), the Laboratory failed to assess the competency of 1 of 1 Technical Consultant (TC) (CMS-209 form listed as personnel 2) for their supervisory responsibilities in 2022 Findings include: 1. On the day of survey, 03/20/2023 at 01:30 pm, the TC could not provide competency assessment records for 1 of 1 TC for their supervisory responsibilities in 2022. 2. The TC confirmed the finding above on 03/20/2023 at 04:40 pm.</p>
D5293	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c)</p> <p>(b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities.</p> <p>This STANDARD is not met as evidenced by: Based on review of Quality Assessment (QA) records and interview with technical consultant (TC) #1, the laboratory failed to document all general laboratory systems quality assessment activities that assesses the laboratory's Preanalytical, Analytical</p>

and Postanalytical systems for 5 of 12 months in 2021 and 12 of 12 months in 2022. Findings include: 1. On the day of survey, 03/20/2023 at 03:55 pm, the laboratory director or designee did not sign the QA record for 5 of 12 months in 2021 (July, August, September, October and November) 2. The laboratory could not provide documentation of the monthly quality assessment activities in 2022. 3. TC #1 confirmed the findings above on 03/20/2023 around 04:40 pm.