Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0181633	07/16/2026
Name of Provider or Supplier	**Street Address, City, State**	
Punxsutawney Area Hospital	81 Hillcrest Drive, Punxsutawney, 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	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 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. This STANDARD is not met as evidenced by: Based on lack of documentation and interviews with Technical Supervisors (TS) # 2 and TS # 4 and Technical Consultant (TC) # 2, the laboratory failed to follow an established competency assessment (CA) policy to assess the competency of 2 of 2 TC for their supervisory responsibilities performed in 2024. Findings Include: 1. The laboratory's CA policy stated, "It is the policy of the Punxsutawney Area Hospital Laboratory to assess competency of all personnel on at 6 months, 1 year, and yearly thereafter ... The Director or the Director's designee will assess the competency of all persons designated as Technical Consultant, Technical Supervisor, or General Supervisor, and document on separate competency". 2. On the first day of survey, 7/15 /2026 at 11:45 am, the laboratory failed to provide CA records to assess the competency of 2 of 2 TC (CMS 209, TC # 2 and TC # 3 dated 6/23/2026), for their supervisory responsibilities performed in the laboratory in 2024. 3. The laboratory performed 465,461 Chemistry tests in 2025 (CMS 116 estimated annual volume, dated 06/23/2026) 4. TS # 2, TS # 4 and TC # 2 confirmed the findings above on 7/16 /2026 at 12:30 pm
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required

	for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on review of the laboratory's American Proficiency Institute (API) proficiency testing (PT) records, lack of documentation and interview with Technical Consultant (TC) #1, the laboratory failed to verify the accuracy of the PT results obtained for 1 of 3 API PT Chemistry testing events in 2025. Findings Include: 1. On the days of survey, 7/15/2026 and 7/16/2026, review of the laboratory's API PT records revealed the laboratory did not verify the accuracy of the following analytes that were not scored by the PT agency for 1 of 3 API Chemistry PT events performed in 2025: - 2025 Chemistry-core 2nd event: Bilirubin, total (CH-07, CH-09, CH-10) 2. The API Proficiency Testing performance Evaluation form stated " Laboratories should review the Performance Summary and Comparative Evaluation thoroughly for failures or 'not graded' analytes. Laboratories are responsible for documenting and performing corrective action for failures and must perform a self-evaluation using statistics presented in the Participant Data Summary for samples that have not been graded.". 3. TC #1 (CMS 209 personnel #2, dated 6/23/2026) confirmed the findings above on 01 /14/2026 at 3:32 pm.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) (e)(4)(iii) All proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratorys performance and to identify any problems that require corrective action; and This STANDARD is not met as evidenced by: Based on review of the laboratory's Pennsylvania Department of Health (PA DOH) Proficiency Testing (PT) records and interview with Technical Consultant (TC) #1, the Laboratory Director (LD) failed to ensure PT reports for 1 of 3 PA DOH PT toxicology events were reviewed by appropriate staff to evaluate the laboratory's performance in 2025. Findings Include: 1. On the days of survey, 7/15/2026 and 7/16 /2026, the laboratory failed to provide documentation of LD/designee PT result review for the following 1 of 3 PA DOH toxicology PT events performed in 2025: - PA DOH Drugs Urine Analysis 2025- III 2. The laboratory performed 465,461 examinations in 2025 (CMS 116 estimated annual volume, dated 6/23/2026). 3. TC #1 (CMS 209 personnel #2, dated 6/23/2026) confirmed the findings above on 7/16/2026 at 1:15 pm.