Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D0393469	03/24/2025
Name of Provider or Supplier	**Street Address, City, State**	
Associated Physicians, Llp	4410 Regent St 1st Flr, Madison, WI	

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 surveyor review of competence evaluation policy and records and interview with the Laboratory Supervisor (Staff A), the laboratory did not ensure they followed their competence evaluation policies. The laboratory did not document annual competence evaluations for three of four laboratory testing personnel and five of five physicians performing provider performed microscopy (PPM) testing. Findings include: 1. Review of the 'Lab Staff Orientation, Training, and Assessment' policy showed the policy stated, "Each employee will be given an evaluation for competency at six months from hire and annually thereafter. 2. Review of competence evaluation records showed: Staff A: no annual competence evaluation after June 2022. Staff D: no annual competence evaluation in 2023. Staff E: Start date May 15, 2023, initial and six-month competence documented, no annual competence evaluation. Staff F: Start date July 15, 2024, initial competence documented, six-month evaluation in process. No records of competence evaluation for the five physician testing personnel that perform PPM testing were available. 3. Interview with Staff A on March 24, 2025, at 1:50 PM confirmed the laboratory did not document competence evaluations annually as required by the laboratory's policy and as specified in the personnel requirements in subpart M.
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) The laboratory director is responsible for the overall operation and administration of

	the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on surveyor review of the submitted Clinical Laboratory Improvement Amendments (CLIA) Application for Certification Form Centers for Medicare and Medicaid Services Form 116 (CMS-116) and laboratory records and interview with the laboratory manager (Staff A), the laboratory director did not ensure notification requirements were met as required at 493.51. Findings include: 1. Review of the CMS-116 submitted for this survey showed the submission included a change of the laboratory director. 2. Review of an email from Staff B to Staff A dated March 6, 2024 at 12:32 PM showed Staff C assumed the role of Laboratory Director and Staff B would function as the Assistant Laboratory Director, effective immediately. 3. Interview with Staff A on March 24, 2025, at 9:20 AM confirmed the laboratory director responsibilities were transferred from Staff B to Staff C on March 6, 2024 but the director did not ensure the laboratory notified Health and Human Services (HHS) or its designee within thirty days of the director change as required at 493.51 (c).