

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 15D2055704	(X3) Date Survey Completed 06/26/2024
Name of Provider or Supplier Advanced Pain Management Of Elwood	Street Address, City, State 2976 N Scatterfield Road, Anderson, IN	
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
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on observation, record review, and interview, the laboratory failed to verify twice annually the accuracy of three (potential of hydrogen [pH], creatinine, and oxidants) of ten analytes tested on the Siemens Pro Chemistry analyzer (serial number 18-1381) twice annually from January 2023 to December 2023. Findings include: 1. During the laboratory tour on 6-26-24 at 10:05 am, a Siemens Pro analyzer (serial # 18-1381) was observed to be in use for testing for urine specimens pH, creatinine, and oxidants. 2. In interview on 6-26-24 at 12:40 PM, SP-01 (Laboratory Director) confirmed they failed to submit one of two proficiency testing evaluations to College of American Pathologist (CAP) in 2023 for the Urine Drug Adulterants pH, creatinine, and oxidants. 3. Review of the CAP "DAI-B 2023 Urine Drug Adulterant" evaluation report indicted pH quantitative had two unacceptable challenges out of three. 4. In interview on 6-26-24 at 12:40 PM, SP-01 further confirmed the pH testing failed for event DAI B and they did not have documentation of any other verifications performed for pH, creatinine, and oxidants for 2023. 5. Upon request for the policy and procedure for twice annual verification for non-regulated analyte on 6/26/2024 at 12:40 PM, SP-01 verified the laboratory does not have a policy. 6. The following patients (pt) had testing performed during 2023 without twice annual verification being performed: a) Pt#3 tests performed on 5-30-23: Creatinine- 214.7mg/dl; pH 5.9; Oxidants- negative. b) Pt#7 tests performed on 4-25-23: Creatinine- 29.8 mg/dL pH= 7.8; Oxidants- negative. 7. Annual test volume for pH, Creatinine, and Oxidant is 86,400</p>