

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  39D2120761	<b>(X3) Date Survey Completed</b>  03/19/2025
<b>Name of Provider or Supplier</b>  Alliance Pharma, Inc	<b>Street Address, City, State</b>  17 Lee Boulevard, Malvern, PA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2014</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b></p> <p>(b)(6) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's College of American Pathologists (CAP) and Pennsylvania Department of Health (DOH) Proficiency Testing (PT) records and interview with the Quality Assessment Manager (QAM), the laboratory failed to ensure the Laboratory Director/designee and testing personnel (TP) signed the PT attestation sheets for 6 of 6 CAP and 3 of 3 DOH PT events performed in 2023 and 2024. Findings Include: 1. On the day of survey, 03/19/2025 at 10:20 am, the laboratory failed to provide attestation statements signed by the LD/designee and TP for the following 6 of 6 CAP and 3 of 3 DOH toxicology PT events performed in 2023 and 2024: 2023: - CAP Urine Toxicology: UT-A, UT-B, UT-C 2024: - CAP Urine Toxicology: UT-A, UT-B, UT-C - DOH drugs in Urine Analysis: I, II, III 2. The laboratory reported an estimated annual test volume of 1999 chemistry examinations performed in 2024 (CMS 116). 3. The QAM confirmed the findings above on 03/19/2025 at 1:00 pm.</p>
<b>D3009</b>	<p><b>FACILITIES</b> CFR(s): 493.1101(c)</p> <p>The laboratory must be in compliance with applicable Federal, State, and local</p>

laboratory requirements.

This STANDARD is not met as evidenced by:

Based on record review and interviews with the Quality Assurance Manager (QAM) and Laboratory Director (LD), the LD failed to be present for a reasonable period of each working day in each laboratory for which he is director as required by Pennsylvania (PA) state regulations for 2 of 2 years from 01/01/2023 to the day of the survey. Findings Include: 1. Pennsylvania State Clinical Laboratory regulation 5.22(g) states "A director shall be present for a reasonable period of each working day in each laboratory for which he is director". 2. On the day of survey, 03/19/2025 at 12:00 pm, interview with the QAM and LD revealed the LD visited the laboratory once every six months from 01/01/2023 to 03/19/2025. 3. The LD confirmed the findings above on 03/19/2025 at 1:00 pm.

**D6091**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1445(e)(4)(iii)

(e)(4)(iii) All proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's 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 College of American Pathologists (CAP) and Pennsylvania Department of Health (DOH) Proficiency Testing (PT) records and interview with the Quality Assessment Manager (QAM), the Laboratory Director (LD) failed to ensure PT reports for 6 of 6 CAP and 3 of 3 DOH PT toxicology events were reviewed by appropriate staff to evaluate the laboratory's performance in 2023 and 2024. Findings Include: 1. On the day of survey, 03/19/2025 at 10:20 am, the laboratory failed to provide documentation of LD/designee PT result review for the following 6 of 6 CAP and 3 of 3 DOH toxicology PT events performed in 2023 and 2024: 2023: - CAP Urine Toxicology: UT-A, UT-B, UT-C 2024: - CAP Urine Toxicology: UT-A, UT-B, UT-C - DOH drugs in Urine Analysis: I, II, III 2. The laboratory reported an estimated annual test volume of 1999 chemistry examinations performed in 2024 (CMS 116). 3. The QAM confirmed the findings above on 03/19/2025 at 1:00 pm.