

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  39D2278293	<b>(X3) Date Survey Completed</b>  01/13/2026
<b>Name of Provider or Supplier</b>  Prism Molecular	<b>Street Address, City, State</b>  1801 Main Street, Suite 104, Blakely, 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>D3009</b>	<p>FACILITIES CFR(s): 493.1101(c)</p> <p>The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements.</p> <p>This STANDARD is not met as evidenced by:</p> <p>A. Based on record review and interview with the Laboratory Director (LD), the LD failed to be present for a reasonable period of each working day in each laboratory for which they were director for 7 of 15 months from 07/26/2024 to 11/01/2025 as required by Pennsylvania (PA) state regulations. Findings include: 1. The PA State 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, 01/13/2026 at 1:58 pm, review of the Laboratory Director Visitation Forms revealed the LD failed to visit the laboratory onsite for 7 of 15 months from 07/26/2024 to 11/01/2025. 3. The LD confirmed the findings above on 01/13/2026 at 2:30 pm. B. Based on review of laboratory records, lack of documentation, and interview with the Laboratory Director (LD), the LD/owner failed to ensure that 1 of 6 laboratory personnel met the minimum experience requirements specified in the Pennsylvania (PA) Clinical Lab Act to perform supervisory responsibilities from 03/18/2024 to the date of the survey. Findings include: 1. On the day of survey, 01/13/2026 at 1:30 pm, review of personnel credentials revealed that TP# 4 obtained a Bachelor of Science degree in Biology in August 2020. 2. Further review of laboratory records revealed that TP #4 reviewed the following documentation: - Quality Assurance Records - Quality Control Records - Temperature Records - Test Logs 3. The laboratory was unable to provide the acceptable documentation of 6 years' experience for TP#4 (CMS 209, dated 01/12/2026) required to perform the duties of a supervisor in the state of Pennsylvania from March 18, 2024, to day of the survey. 4. TP# 4 confirmed the findings above on 01/13/2026 at 02:00 pm.</p>

**D5429**

**MAINTENANCE AND FUNCTION CHECKS**

CFR(s): 493.1254(a)(1)

(a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:

Based on lack of maintenance records, observation and interview with the Laboratory Director (LD), the laboratory failed to perform and document the maintenance and function checks as defined by the manufacturer for 4 of 4 traceable timers for assay procedures, 5 of 5 traceable monitoring hygrometers and 7 of 7 traceable thermometers used to ensure acceptable storage and operating temperatures were met in the Bacteriology/Virology departments from 03/02/2025 to 01/13/2026. Findings include: 1. On the day of the survey, 01/13/2026 at 2:00pm, the laboratory failed to provide documentation of maintenance and function checks performed for the following: in bacteriology/virology departments in 2025 and 2026. - 5 of 5 Room Temperature thermometer (s/n 230428035, 230428032, 230428036, 230428037, 230428034) due 23 Jun 2025 -7 of 7 Refrigerator thermometer (s/n 230429136, 230429119, 230429146, 230429110, 230429138, 230429148, 230249,129) due 26 Jun 2025 - 4 of 4 Traceable timers (s/n 230150483, 230150424, 230150615, 23015483) due 02 Mar 2025 2. The LD confirmed the above findings on 01/13/2026 at 2:30 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 College of American Pathologists (CAP) proficiency testing (PT) records and interview with the Laboratory Director, (LD) the laboratory failed to ensure review and evaluation of the results obtained for 18 of 18 CAP Microbiology PT events performed in 2024 and 2025. Findings: 1. On the day of survey, 01/13/2026 at 1:30 pm review of CAP PT records revealed the LD/designee failed to document the review and evaluation of the laboratory's performance for the following CAP PT testing reports received in 2024 and 2025: - 6 of 6 Bacteriology Events in 2024 and 2025 - 3 of 3 Mycology Events in 2025 - 3 of 3 Parasitology Events in 2025 - 6 of 6 Virology Events in 2024 and 2025 2. The laboratory performed 17,612 (CMS 116 estimated volume, dated 01/12/2026) microbiology tests in 2025. 3. The LD confirmed the findings above on 01/13/2026 at 2:30 pm.