| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 39D0190807 | 09/10/2026 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Planned Parenthood Keystone-Allentown | 29 N 9th Street, Allentown, 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 |
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| **D3009** | FACILITIES<br>CFR(s): 493.1101(c)<br><br>The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements.<br><br>This STANDARD is not met as evidenced by:<br>A. Based on lack of documentation and interview with the Regulatory Affairs Manager (RAM), the laboratory failed to monitor and document room temperature and relative humidity for 2 of 2 years to ensure substantial proof of efficacy was provided for reagents and operating conditions were met for reliable test system operation when chemistry and bacteriology testing was performed from 9/10/2024 to 9/10/2026. Findings include: 1. On the day of survey, 9/10/2026 at 11:30 am, the laboratory could not provide documentation for monitoring room temperature and relative humidity for 2 of 2 years to ensure proper storage of reagents and operating conditions were met for the following reagents and instrumentation used in the laboratory from 9/10/2024 to 9/10/2026: - McKesson Consult Diagnostics hCG urine dipstick tests (manufacturer's acceptable temperature range: 2C to 30C) - Siemens Uristix 4 reagent test strips (manufacturer's acceptable temperature range: 15C to 30C) - 1 of 1 Binx Health io CT/NG instrument (manufacturer's acceptable temperature range: 5C to 40 C, manufacturer's acceptable humidity range: less than 80% RH) 2. The laboratory performed 3,636 waived tests in 2025 (CMS 116 estimated annual volume, dated 08/28/2026). 3. The RAM confirmed the findings above on 9/10/2026 at 12:45 pm. B. Based on review of the laboratory's temperature logs, refrigerator temperature monitoring policy, lack of documentation, and interview with the Regulatory Affairs Manager (RAM), the laboratory failed to document corrective action taken when refrigerator storage temperatures were recorded outside of the laboratory's acceptable range of 36-46 degrees Fahrenheit (F) for reagents used when bacteriology testing (Rapid CT/NG screen) was performed for 24 of 82 days from 01/01/2025 to 04/29/2026. Findings include: 1. On the day of the survey, 09/10 |

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| | /26 at 12:00 pm, review of the laboratory's refrigerator temperature logs revealed reagent storage temperatures for the Binx io analyzer were recorded outside of the laboratory's acceptable range of 36-46 F for the following 24 of 82 days when Rapid CT/NG screening was performed from 01/01/2025 to 04/29/2026: - 1/31/25 (46.6 F) - 2/12/25 (46.8 F) - 2/14/25 (46.2 F) - 2/21/25 (46.2 F) - 2/26/25 (46.8 F, 47.7 F) - 3/11 /25 (47.7 F) - 3/23/25 (46.9 F) - 5/7/25 (47.8 F) - 5/21/25 (48.2 F) - 5/30/25 (47.5 F) - 6/18/25 (46.8 F) - 6/20/25 (48.0 F) - 7/9/25 (46.6 F, 48.2 F) - 8/6/25 (48.2 F) - 8/13/25 (46.9 F) - 9/3/25 (48.2 F) - 9/24/25 (47.7 F) - 1/14/26 (47.1 F) - 1/21/25 (48.2 F) - 1/28 /26 (47.7 F, 47.8 F) - 3/4/26 (47.5 F) - 3/11/26 (46.2 F) - 4/1/26 (46.5 F, 47.7 F) - 4/22 /26 (46.2 F) 2. The laboratory's Refrigerator Temperature Monitoring policy stated, "Any action steps taken to rectify the out-of-range temperature must be documented on the log". 3. On the day of the survey, 9/10/2026, the laboratory could not provide documentation of corrective actions taken when refrigerator temperatures were recorded outside of the laboratory's acceptable range. 4. The laboratory performed 3,636 waived tests in 2025 (CMS 116 estimated annual volume, dated 08/28/2026). 5. The RAM confirmed the above findings on 09/10/2026 at 12:30 pm. |