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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 33D2014197 | (X3) Date Survey Completed 04/02/2025 |
| Name of Provider or Supplier Pediatric And Adolescent Urgent Care Of Wny Pllc | Street Address, City, State 1800 Maple Road, Suite 100, Williamsville, NY | |
| 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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| D5781 | <p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on review of temperature log sheets, Standard Operating Procedures (SOPs), test kit manufacturer's package inserts, lack of corrective action records, as well as interview with the Laboratory Manager (LM), the laboratory failed to perform and document corrective action for out-of-range temperatures. FINDINGS: 1. Documented ambient room temperature deviated from the specified range of 68F - 78F for multiple dates in the laboratory where test kits, reagents were stored, and patient specimen testing was performed. 2. There was no documentation of corrective action performance for out-of-range ambient laboratory temperatures. 3. This is contrary to instructions included in the current, approved SOPs. 4. The LM confirmed the findings on April 2, 2025, at approximately 3:30 P.M.</p> |