

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D2151213	(X3) Date Survey Completed 03/10/2026
Name of Provider or Supplier West Hills Pediatrics	Street Address, City, State 1781 Pine Hollow Rd, Mckees Rocks, 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
D5211	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing (PT) policy, Wisconsin State Laboratory of Hygiene (WSLH) PT records, and interview with the Medical Assistant (MA), the laboratory failed to review and evaluate the PT results obtained for 1 of 3 WSLH Bacti_Viral events performed in 2025. Findings: 1. The laboratory's Proficiency Testing Policy stated, "The lab evaluates the accuracy of any analyte that is not scored by the lab's PT program." 2. On the day of survey, 3/10/2026 at 09:30 am, review of the laboratory's WSLH PT results revealed the laboratory failed to review and evaluate the PT results not graded by the PT agency for the following 1 of 3 WSLH Bacti_Viral events performed in 2025: - WSLH PT 2025-Bacti_Viral Event #1: Module 5170, Group A Strep, ST-4 3. The MA confirmed the findings above on 3 /10/2026 at 11:00 am.</p>
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p>

This STANDARD is not met as evidenced by:
Based on review of the laboratory's temperature logs, lack of documentation, and interview with the Medical Assistant (MA), the laboratory failed to monitor and document room humidity to ensure operating conditions were met for 1 of 1 Quincy Lab, Inc. Model 10-180 Incubator used to incubate throat cultures from 07/16/2024 to date of survey. Findings include: 1. The manufacturer's operating environment specifications stated: "80% RH maximum." 2. On the date of the survey, 3/10/2026 at 10:00 am, the laboratory failed to provide documentation for monitoring of room humidity to ensure operating conditions were met for the following incubator used to incubate throat culture plates from 07/16/2024 to 3/10/2026: - 1 of 1 Quincy Lab, Inc. Incubator, Model 10-180 3. The laboratory performed 34 Microbiology tests in 2025. (CMS-116 estimated annual volume, dated 2/19/2026). 4. The MA confirmed the findings above on 3/10/2026 at 10:45 am.

D5471

CONTROL PROCEDURES
CFR(s): 493.1256(e)(1)(g)

(e) For reagent, media, and supply checks, the laboratory must do the following: (e)
(1) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable.

This STANDARD is not met as evidenced by:
Based on lack of Quality Control documentation and interview with the Medical assistant (MA), the laboratory failed to document a positive and negative reactivity for 1 of 2 lots/shipments of Bacitracin (A) Discs used for throat culture testing from 06/25/2025 to the date of survey. Findings include: 1. On the day of survey, 03/10/2026 at 10:45am, the laboratory could not provide the records for the positive and negative reactivity checks performed for 1 of 2 lots/shipments of Bacitracin (A) Discs (lot# 4123262) used for throat culture testing from 06/25/2025 to 03/10/2026. 2. Review of the laboratory's test logs revealed the laboratory performed throat cultures for 71 patients from 06/25/2025 to 03/10/2026. 3. The MA confirmed the findings above on 03/10/2026 at 11:00 am.