

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D2071808	(X3) Date Survey Completed 08/12/2025
Name of Provider or Supplier Freedom Pathology Partners, Llc	Street Address, City, State 524 East Elm St, Suite A, Conshohocken, 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
D3009	<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: Based on observation, record review, and interview with the Laboratory Supervisor (LS), the laboratory director (LD) failed to ensure that the laboratory was in compliance with Pennsylvania Department of Health (PA DOH) directives and regulatory requirements prior to the start of patient testing for 1 of 1 chemistry test performed from 08/28/2024 to the date of the survey. Findings Include: 1. On the day of survey, 08/12/2025 at 10:15 a.m., observation of the laboratory and interview with the LS revealed the laboratory performed macroscopic urinalysis examinations (Dipstick) from 08/28/2024 to the date of the survey. 2. Review of the laboratory's PA Clinical Laboratory permit (issued 08/15/2024) revealed Dipstick urinalysis testing was not currently listed as an approved test. 3. The laboratory failed to provide documentation of approval by the PA DOH to perform 1 of 1 chemistry test (Dipstick urinalysis) prior to the start of patient testing from 08/28/2024 to 08/12/2025. 4. The LS confirmed the findings above on 08/12/2025 at 10:35 a.m.</p>
D5213	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1)</p> <p>(b) The laboratory must verify the accuracy of the following: (b)(1) Any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on review of the laboratory's American Proficiency Institute (API) proficiency testing (PT) records and interview with the Laboratory Supervisor (LS), the laboratory failed to verify the accuracy of the PT results that were not graded for 7 of 7 API PT Performance Evaluation reports reviewed for microbiology testing events performed from 2023 to 2025. Findings: 1. The API Proficiency Testing performance Evaluation form stated "Laboratories are responsible for documenting and performing corrective action for failures and must perform a self-evaluation using statistics presented in the Participant Data Summary for samples that have not been graded." 2. On the day of survey, 08/12/2025 at 09:30 am, review of the laboratory's API PT Performance Evaluation records revealed the laboratory failed to verify the accuracy or perform a self-evaluation for analytes that were not graded by the PT agency for the following 7 of 7 API PT Performance Evaluation reports reviewed on site for microbiology API PT events performed from 2023 to 2025: 3. The LS confirmed the finding above on 8/12/2025 at 10:35 am

D5413

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(b)

(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.

This STANDARD is not met as evidenced by:
Based on lack of documentation, and interview with the Laboratory Supervisor (LS), the laboratory failed to monitor the room temperature and humidity to ensure proper operating conditions where microbiology specimens are received, stored and tests were performed for for 6 of 6 laboratory areas in 2024. Findings include: 1. On the day of survey, 8/12/2025, at 10:00 am, the laboratory temperature logs revealed the laboratory failed to document room temperature and humidity for the following 6 of 6 laboratory areas where microbiology specimens are received, stored and testing was performed in 2024: - Office Area: 13 days of humidity 3 days of room temperature - Upper shipping Area: 75 days of humidity 67 days of room temperatures -LAB space: 16 days of humidity 6 days of room temperature - Receiving room #1: 15 days of humidity 6 days of room temperatures - Receiving room #2: 19 days of humidity 3 days of room temperature -Basement storage: 12 days of humidity 3 days of room temperature 2. The laboratory performed 19,000 total microbiology tests in 2024 (CMS 116, estimated annual volume, dated 08/12/2025). 3. The LS confirmed the findings above on 8/12/2025 at 10:35 am.