Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	07D2017623	03/25/2025
Name of Provider or Supplier	**Street Address, City, State**	
Ppsne Lab	345 Whitney Ave, New Haven, CT	

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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to establish competency assessment policy and procedures to assess competency for the regulatory responsibilities of the general supervisor (GS) in the specialty of microbiology. Findings include: 1. Record review on 03/25/2025 of the staff 'training and competency files' revealed lack of competency assessment documentation for the regulatory position of the GS. 2. Record review on 03/25/2025 of the laboratory's standard operating procedures revealed lack of an established competency assessment policy and procedures to assess competency for the regulatory positions and defining frequency of such assessment. 3. Staff interview on 03/25/2025 at 10:00 AM with the laboratory's general supervisor confirmed the above finding. The GS further commented that he/she was unaware of this requirement. 4. The laboratory performs 93,816 tests annually in the specialty of microbiology.
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 surveyor observation, record review and staff interview, the laboratory failed to define and provide evidence of monitoring and documenting room temperature requirements in the specialty of microbiology. Findings include: 1. Surveyor observation on 03/25/2025 at 11:50 AM of the laboratory storage room revealed the following stored consumables: a. 'Aptima Specimen Transfer Kit' b. 'Hologic Aptima Assay Fluids' 2. Record review on 03/25/2025 of the 'Aptima Specimen Transfer Kit' and 'Hologic Aptima Assay Fluids' package inserts revealed an acceptable room temperature storage requirement between 15 to 30 degrees Celsius. 3. Record review on 03/25/2025 of the laboratory's maintenance records for 2024 and 2025 revealed lack of documentation of room temperature for the laboratory's storage area. 4. Staff interview on 03/25/2025 at 11:55 AM with the laboratory's general supervisor confirmed the above findings. The GS further commented that he/she was unaware of this requirement. 5. The laboratory performs 93,816 tests annually in the specialty of microbiology.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. This STANDARD is not met as evidenced by: Based on surveyor observation, record review and staff interview, the laboratory failed to establish a system to evaluate and compare test results between two instruments twice annually in the specialty of microbiology. Findings include: 1. Surveyor observation on 03/25/2025 at 9:30 AM of the laboratory's work area revealed 2 of 2 Hologic Panther DNA Amplification Analyzer Systems in use. 2. Record review on 03/25/2025 of the laboratory's maintenance records for 2024 and 2025 revealed the lack of documentation of test result comparison between the above two instruments at least twice annually. 3. Record review on 03/25/2025 of the laboratory's standard operating procedures revealed lack of policies and procedures to assess tests results between the two instruments and defining frequency of the evaluation. 4. Staff interview on 03/25/2025 at 12:00 PM with the laboratory's general supervisor confirmed the above finding. The GS further commented that he/she was unaware of this requirement. 5. The laboratory performs 93,816 tests annually in the specialty of microbiology.