Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D0126129	08/08/2024
Name of Provider or Supplier	**Street Address, City, State**	
Prophase Diagnostic Laboratory	42 Throckmorton Ln, Old Bridge, NJ	

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
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the General Supervisor (GS), the laboratory lacked work records and signed attestation records for American Proficiency Institute (API) PT events for SARS-CoV-2 liquid molecular tests in calendar years 2023 and 2024. The findings include: 1. There were no work records or signed attestion records available for review for the following PT events for SARS-CoV-2 liquid molecular tests: a) 2024 Microbiology 1st event b) 2024 Microbiology 2nd event c) 2023 Microbiology 1st event d) 2023 Microbiology 2nd event e) 2023 Microbiology 3rd event 2. The GS confirmed on 8/8 /24 at 11:35 am that work records and signed attestation records were not available for reveiw for the PT events mentioned above.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented.

	This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the General Supervisor (GS), the laboratory failed to document the evaluation of all incorrect scores and corrective action taken for the 3rd Microbiology event of 2023 with the American Proficiency Institute (API). The findings include: 1. The laboratory received a 50% score for SARS-CoV-2 liquid molecular for the 3rd Microbiology event of 2023. 2. There was no documented evidence for evaluation or corrective action performed for the aforementioned PT event. 3. The GS confirmed on 8/8/24 at 1:15 pm, the laboratory failed to evaluate and perform corrective action for the 3rd Microbiology event of 2023.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on surveyor observation of the laboratory and interview with the General Supervisor (GS), the laboratory failed to discard expired Taqman Open Array Respiratory Tract Microbiota Plates from 8/20/21 to 8/8/24. The findings include: 1. The laboratory failed to discard Taqman Microbiota Plates Lot #3832802 which expired on 8/20/21. 2. The GS confirmed on 8/8/24 at 11:30 am that the laboratory failed to discard the expired reagents.