Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D2158103	08/25/2025
Name of Provider or Supplier	**Street Address, City, State**	
Phi Life Sciences	4701 Melbourne Place Suite A2, College Park, MD	

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
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(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: (1) Water quality. (2) Temperature. (3) Humidity. (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 review of laboratory records and interview with the testing person (TP), the laboratory failed to monitor temperature and humidity in the laboratory where reagents were stored and molecular testing was performed. Findings: 1. There were no records for room temperature and humidity in the laboratory where extraction and amplification reagent kits were stored and molecular testing was performed. 2. During the exit interview on 08/07/2025 at 2:30 PM, the TP confirmed that temperature and humidity was not monitored in the laboratory where reagents were stored and molecular testing was performed.
D5453	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(iv)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each test system that has an extraction phase, include two control materials, including one that is capable of detecting errors in the extraction process; (g) The laboratory must document all control procedures performed.

	This STANDARD is not met as evidenced by: Based on interview with the testing person (TP), the laboratory failed to test a negative extraction control for the molecular severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), influenza (Flu), and respiratory syncytial virus (RSV) assay. Findings: 1. The laboratory extracted nucleic acids from patient specimens prior to performing the SARS-CoV-2/Flu/RSV molecular assay. 2. During the initial survey on 08/07/2025 at 1:06 PM, the TP confirmed that a negative control was not run through the extraction phase of testing.
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Based on review of patient test reports, electronic requisitions, and the laboratory information management system (LIMS) and interview with the chief executive officer (CEO), the laboratory failed to ensure that the LIMS did not allow a single patient specimen with a unique accession number to have two collection, receipt, and reporting dates. Findings: 1. The laboratory had a primary location in Charleston, South Carolina (SC) and the laboratory that was surveyed in College Park, Maryland (MD). 2. The test report for patient 331286033 showed that the specimen was collected on 08/01/2025, received on 08/04/2025, and reported on 08/04/2025. 3. The electronic requisition showed that the specimen was collected on 07/11/2025 and the LIMS system showed that the specimen was reported on 07/16/2025. 4. The testing plate also included patients 331285242, 331285198, 331286085, and 331286094. All patients were documented as received and reported on 08/04/2025 from the MD laboratory. 5. At 1:40 PM the CEO confirmed that the laboratory in Charleston, SC was sending specimens for testing and for cross-validation of that assay and that only two specimens on the testing plate, patients 331285198 and 331286085, were for patient testing. The other three specimens had already been tested and reported in Charleston, SC and were sent up for cross-validation of the assay. However, all five specimens, were tested and results reported from the MD laboratory so that the three specimens that were originally tested and reported in Charleston, SC, (331286033, 331285242, and 331286094) were reported twice, once from each of the two separate locations. The LIMS allowed the single specimens with unique accession numbers to have two collection, receipt, and reporting dates.