Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 49D2271909	**(X3) Date Survey Completed** 05/01/2023
Name of Provider or Supplier New Life Medicine	**Street Address, City, State** 1662 Bonham Road, Bristol, VA	
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**
D0000	An announced CLIA Initial survey was conducted at the New Life Medicine on 05/01/23 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows: The laboratory was not in compliance with the following 42 CFR part 493 CLIA Regulations: D3000 - 42 C.F.R. 493-1100 Condition: Facilities Administration.
D3000	FACILITY ADMINISTRATION CFR(s): 493.1100 Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe. This CONDITION is not met as evidenced by: Based on a tour of the laboratory, staff meeting document, policy and procedures (P&P), manufacturer operation guide, room temperature records, email communications, daily patient test data, and interviews, the laboratory failed to provide adequate workbench space and ventilation to safely conduct pre-analytical, analytical and post-analytical phases of toxicology testing from 01/01/23 up to date of survey on 05/01/23. Refer to D3001.
D3001	FACILITIES CFR(s): 493.1101(a)(1)

The laboratory must be constructed, arranged, and maintained to ensure the space, ventilation, and utilities necessary for conducting all phases of the testing process.

This STANDARD is not met as evidenced by:
Based on a tour of the laboratory, staff meeting document, policy and procedures (P&P), manufacturer operation guide, room temperature records, email communications, daily patient test data, and interviews, the laboratory failed to provide adequate workbench space and ventilation to safely conduct pre-analytical, analytical and post-analytical phases of toxicology testing from 01/01/23 up to date of survey on 05/01/23, reporting 3,235 patients. Findings include: 1. An entrance tour and interview with the primary testing personnel (TP) and compliance specialist on 05 /01/23 at approximately 09:45 AM revealed a testing room approximately 20 by 30 feet, with a large bay roll door and single door entrance on left side wall. The bay roll door and single entrance door lead to an outside parking lot. The single entrance door was propped open by a metal rod approximately 9 inches long and three inches wide. An American Standard Heating/Cooling Return unit was positioned on the same wall inside the laboratory, occupying approximately five by four feet of laboratory space. A ceiling air vent was in the middle of the laboratory testing space. Two industrial electrical cords hung freely from the tiles in the ceiling approximately four feet, with one of the ceiling tiles askew and the cord touching a tubular fluorescent lightbulb. Both cords had a four-way electrical box (110 volt) attached with no visible conduit or fixed column. During the same tour, the inspector noted the digital room thermometer located at the workbench in front of the heating/cooling return unit read 25 degrees Celsius. The inspector could physically feel warm air blowing down from the ceiling air vent. The inspector noted that the two free-hanging four-way electrical boxes were located above the two workbenches. Workbench A included a Yamato (IC103C) incubator, Eppendorf 5430 centrifuge, vortex mixer, 4 Eppendorf pipettes, one Sartorius pipette and pipette tips. The incubator, vortex mixer and centrifuge were plugged into the four-way hanging electrical box that was positioned approximately three feet above the workbench. Patient samples and test chemical reagents are processed on the workbench for the Shimadzu 8040 Ultra-High Performance Liquid Chromatography/Tandem Mass Spectrometry (UHPLC/MS/MS) toxicology testing. Workbench B included a Drucker Model 614B centrifuge, label printer and computer plugged into the free hanging electrical box. Patient samples are processed on the workbench for the UHPLC/MS/MS toxicology testing. 2. An interview with the primary TP on 05/01/23 at approximately 11:00 AM revealed staff must prop the single entrance door open to allow cool air to flow into the laboratory at the start of each day of testing. The inspector inquired about notification to the administrator of the building and compliance specialist regarding the temperature issue within the lab. They stated, "We have notified the administrator and compliance specialist of the issues." The inspector requested to review documentation of the notifications. An email from the primary TP to the Assistant Vice President of Sales on 03/02/23 stated, " We have brought to the attention of the clinic staff how hot it is getting in the laboratory. There have been days here lately where the lab exceeds the requirements for room temp and refrigerator temps. The last few days when I come in the temp has been 27 degrees Celsius or 80 degrees Fahrenheit." An email was sent to the same individual on 03/27/23 from the primary TP stating, "the lab temp this morning got as high 29 degrees Celsius (85 F). The upper limit of operating conditions is 25." A third email was sent on 04/26/23 from the same TP to the same individual stating, "Can you please inquire about the timeline concerning the HVAC/temperature issue at New Life Medicine SLP lab? Last we were told was is that it would be addressed before

	"summer" temperatures get here. Nothing has been done thus far." 3. A review of the staff meeting document written by the compliance specialist for Select Laboratory Partners and dated 03/17/23 stated, "On March 17, 2023, I made my quarterly visit to New Life Medicine and also to see if anything needed attention before their first inspection. Upon entering, I noticed that there are two areas of the lab, where long cords with outlets are hanging from the ceiling. There are free and not attached or secured to anything. There is also an outlet right beside the sink, where water could easily enter the outlet. I as well as the staff would like these issues to be addressed. I feel the hanging outlets need to be pulled down and attached in some way to their work surfaces. The outlet at the sink is a ground fault, so it may be ok. (2.) There are also concerns about the HVAC unit in the building. The temperature reached 82 degrees in the lab last week and was making a horrible noise. Lab personnel got one of the office staff to listen to the noise as well. The employees have expressed their concern to the practice and have been told that they got an estimate to get the HVAC fixed and are now looking for a second estimate. I suggest maybe a portable A/C unit, until this matter is resolved. " The lab director signed the document on 03/17/23. 4. Review of the P&P, "TOX-LCMS-014 Alternate Confirmatory Urine Testing Procedure", revealed that Mobile Phase A and B and reagent rinses are to be kept at the established room temperature of 20-25 degrees Celsius. The working calibration standards, working quality control standards, mixed internal stock solutions, and patient samples are to be maintained at the established room temperature for the pre-analytical and analytical testing phases. Review of P&P, "CMP-001 General Policy, Section 2- Safety", revealed the following statements, "The laboratory must be constructed, arranged, and maintained to ensure the space, ventilation, and utilities necessary for conduction of all phases of testing are adequate." 5. Review of the Shimadzu UHPLC/MS/MS operator's guide revealed the manufacturer defined operating temperature of 18-28 degrees Celsius. 6. Review of room temperature logs from 01/01/23 up to date of survey on 05/01/23 revealed two dates in which the lab recorded room temperatures > 25 degrees Celsius: 02/06/23 and 02/15/23. Additional review of the records revealed temperatures at 25 degrees Celsius for six days in February, four days in March and one day in April. The inspector inquired about how the lab records the room temperatures each day and referenced the email sent on 03/02/23 and 03/27/23 indicating that the room temperatures are above the established range upon entrance into the lab. The room temperature logs did not reflect the high temperatures. The primary TP stated, "When I come in, I review the room temperature and must prop the door open. The room temperature is above 25 degrees Celsius. After the door has been propped open to get cooler air in and I start up the instruments. I record the room temperature after the door has been opened." 7. Review of daily patient testing data from the laboratory information system (LIS) revealed the laboratory began patient testing on 01/19/23. The laboratory received, processed and reported 351 patients in January 2023, 849 patients in February 2023, 1091 patients in March 2023, and 944 patients in April 2023. Total of 3,235 patients. 8. An exit tour at approximately 1315 on 05/01/23 revealed lack of splash guards or fixed columns for the two hanging four-way electrical boxes on or near the two workbenches that are used to prepare chemical reagents and patient samples. 9. An exit interview with the compliance specialist, Vice president of Technical Services, and the lab director on 05/01/23 at approximately 1345 confirmed the findings.