

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D2257480	(X3) Date Survey Completed 06/09/2026
Name of Provider or Supplier Spero Health Virginia Core Lab	Street Address, City, State 5631 S Laburnam Ave, Richmond, 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 recertification survey was conducted at Spero Health Virginia Core Lab on June 9, 2026 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. Spero Health Virginia Core Lab was not in compliance with the applicable Conditions and Standards under 42 CFR part 493 CLIA Regulations. Specific deficiencies are as follows:
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) (b)(1)(i) Establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (b)(1)(ii) Perform and document the maintenance activities specified in paragraph b(1)(i) of this section. This STANDARD is not met as evidenced by: Based on a laboratory tour, review of Instrument logs, Quality Control (QC) records and interview, the laboratory failed to follow their established process to record incubator temperature and pressures for the Mass Spectrometer on twenty-seven (27) testing days in calendar year 2025. Findings include: 1. During an initial laboratory tour with the lab manager on 6/09/26 at 9:15 am, it was revealed the laboratory utilizes the AB Sciex Triple Quad 4500 Mass Spectrometer (ABSX1) for high complexity drug testing. 2. A review of lab's Daily LC-MSMS Instrument log revealed the laboratory records ABSX1 Nitrogen Pressure, Incubator temp, Pump A & B pressures each day of testing. 3. A review of the 2025 QC records for the ABSX1 and the corresponding 2025 instrument logs revealed the lab failed to document daily maintenance on the following 27 dates in 2025: January 13, 15, 19; February 7, 19; March 17, 23; April 23, 28; May 2, 12, 21; June 13; July 3, 10, 16; August 4, 14, 29; September 10, 22, 24, 29; October 7, 15; November 30; and December 10. 4. In an interview with the lab manager at 4:30 pm, it was explained that maintenance is

performed each morning. QC is ordered in their information system, specimens spiked, run and evaluated each day of patient testing on the Mass Spectrometer. QC is not run if there are no patients.