Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2254939	05/02/2025
Name of Provider or Supplier	**Street Address, City, State**	
Prosperity Labs Llc	13890 Braddock Rd Suite 201, Centreville, 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 Prosperity Labs, LLC on April 30, 2025 to May 2, 2025 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 and includes the Condition under 42 CFR part 493 CLIA Regulation: D6134-42 CFR. 493.1453 Clinical Consultant.
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 a review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), policy and procedure manual, personnel records, and interview, the laboratory did not establish and follow a policy for one (1) of 1 Clinical Consultant competency assessment from December 2023 until May 2025. The findings include: 1. Review of the CMS 209 revealed the laboratory director (LD) identified a Clinical Consultant (CC) for the specialty of Microbiology. 2. Review of the laboratory policy and procedure manual revealed a lack of a policy outlining the documentation of the competency assessment of the Clinical Consultant. 3. Review of the laboratory's personnel records revealed the LD failed to document the competency assessment for the Clinical Consultant from December 2023 until May 2025. The surveyor requested to review the competency assessments for the CC. The laboratory provided no documentation for review. 4. In an exit interview with the Technical Supervisor on May 1, 2025 at 11:45 AM, the above findings were confirmed.
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 tour of the laboratory, review of the laboratory's policy and procedures, centrifuge records, lack of documentation, and interviews, the laboratory failed to follow their established policy for performing annual revolutions per minute (RPM) checks for one of one VWR high speed microcentrifuge for calendar year 2024. The findings include: 1. A tour of the laboratory testing area on April 30, 2025 at 9:00 AM revealed the laboratory used the VWR high speed microcentrifuge (serial number 110063054-00210) to centrifuge patient specimens during the extraction phase of the protocol for the determination of Urinary Tract & Vaginitis Pathogens using Real-Time Polymerase Chain Reaction (RT-PCR). 2. Review of the laboratory's policies and procedures revealed protocols for "Determination of Urinary Tract Infection Pathogens using Real-Time Polymerase Chain Reaction (RT-PCR) and Determination of STI & Vaginitis Pathogens using Real-Time Polymerase Chain Reaction (RT-PCR)", with the following statement, "15.3. Centrifuge Calibration, 15.3.1. The centrifuge used to extract the samples must be verified annually." 3. Review of available RPM checks for the microcentrifuge revealed the verification was performed on 04/17/2025. The surveyor requested to review the RPM verification for 2024. The laboratory provided no documentation for review. 4. In an exit interview with the Technical Supervisor on May 1, 2025 at 11:45 AM, the above findings were confirmed.
D6134	CLINICAL CONSULTANT CFR(s): 493.1453 The laboratory must have a clinical consultant who meets the requirements of 493. 1455 of this subpart and provides clinical consultation in accordance with 493.1457 of this subpart. This CONDITION is not met as evidenced by: Based on a review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report form, available personnel records, lack of documentation, and an interview, the laboratory failed to ensure one of one Clinical Consultant possessed the required qualifications for a Clinical Consultant from September 2024 until May 2025. See D 6135.
D6135	CLINICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1455 The clinical consultant must be qualified to consult with and render opinions to the laboratory's clients concerning the diagnosis, treatment and management of patient care. The clinical consultant must-- (a) Be qualified as a laboratory director under 493. 1443(b)(1), (2), or (3) for the subspecialty of oral pathology, 493.1443(b)(5); or (b) Be a doctor of medicine, doctor of osteopathy, doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is

	located. This STANDARD is not met as evidenced by: Based on a review of the Centers for Medicare and Medicaid Services Personnel Report Form (CMS 209), personnel files, Virginia (VA) Medical license look-up and interview, the laboratory failed to ensure the individual listed as a Clinical Consultant possessed the required qualifications for one (1) of 1 Clinical Consultants from September 2024 until May 2025. The findings include: 1. Review of the laboratory's CMS 209 form revealed the listing of one Clinical Consultant (CC). 2. Review of the laboratory personnel file for the Clinical Consultant revealed they possessed a "Doctor of Medicine" degree. The surveyor requested to review the CC's VA medical license. The laboratory provided a Virginia (VA) medical license certificate with no expiration date. 3. A review of the "Virginia Department of Health Professions License Lookup" revealed the CC's "License Status" was listed as "Suspended". After reviewing the documents attached to the lookup, it was determined the license was suspended on 09 /09/2024. 4. In a phone call with the Technical Supervisor on May 2, 2025 at 9:00 AM, the findings were confirmed.