

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2124997	(X3) Date Survey Completed 09/09/2025
Name of Provider or Supplier Ohm Labs Llc	Street Address, City, State 2340 Sw Poma Dr, Palm City, FL	
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 Ohm Labs Llc on June 3, 2025 to September 9, 2025. The laboratory was not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
D3037	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4)</p> <p>(a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to retain their proficiency testing record for the second event of Toxicology in the specialty of Chemistry in 2023. Findings Included: Review of Chemistry proficiency testing revealed there was no documentation for the second event of toxicology proficiency testing for 2023. On 6/3/2025 at 2:08 PM, Technologist B confirmed the second event from 2023 for toxicology could not be located.</p>
D5201	<p>CONFIDENTIALITY OF PATIENT INFORMATION CFR(s): 493.1231</p> <p>The laboratory must ensure confidentiality of patient information throughout all phases of the total testing process that are under the laboratory's control.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to have separate user identifications for using the Indiko Plus instrument for patient chemistry testing. Findings Included: On 6/03/2025 at 3:52 PM, the Indiko Plus Instrument had</p>

unknown username linked to all digitally transmitted chemistry reports. There were no unique usernames and the technologists were using the same usernames for testing on the instrument. Review of LIS manual revealed there was no policy for identifying users on the Indiko Plus instrument. On 6/4/2025 at 11:56 AM, Technologist A confirmed none of the technologists had a separate usernames when using the Indiko Plus Instrument.