Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0953493	09/05/2024
Name of Provider or Supplier	**Street Address, City, State**	
Adov Llc	7813 Shrader Road, 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 ADOV, LLC on September 5, 2024 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. Specific deficiencies cited are as follows:
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on a review of the laboratory's Centers for Medicare and Medicaid Services Laboratory Personnel Report Form (CMS 209), proficiency testing (PT) logs, lack of documentation, and interview, the laboratory failed to verify twice annual accuracy of dermatology KOH microscopy testing in calendar year 2023 and up to the date of the recertification survey on September 5, 2024 for three (3) of 3 testing personnel (TP). Findings include: 1. Review of the laboratory's CMS 209 form revealed that the laboratory director identified three TP (TP #1 - #3) who performed dermatology patient KOH microscopy examinations during the twenty-two month review (November 4, 2022 to 9/5/24). *See Testing Personnel Code Sheet. 2. Review of the available split sample PT records for calendar year 2023 and year to date revealed no documentation of KOH split sample testing or proficiency records. The inspector requested to review KOH microscopy twice annual accuracy verification records for the timeframe outlined above. No documentation was available for review. 3. An interview with the clinical coordinator on 9/5/24 at 12 noon confirmed the above findings.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d)

	Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on a review of the laboratory's Centers for Medicare and Medicaid Services CLIA Application Form (CMS 116), procedure manual, lack of documentation, and interviews, the laboratory failed to ensure the Potassium Hydroxide (KOH) Examination of Skin, Hair, or Nails Procedure was reviewed/ approved by the new laboratory director (LD) for twenty-two (22) of 22 months after a LD change occurred on November 3, 2022. Findings include: 1. A review of the laboratory's CMS 116 form revealed patient KOH microscopy mycology examination was a provided speciality on the testing menu for the 22 month review timeframe (November 4, 2022 to 9/5/24). 2. Review of the laboratory procedure manual revealed a protocol titled: "Potassium Hydroxide (KOH) Examination of Skin, Hair, or Nails Procedure". The procedure was not signed as reviewed/approved by the current LD. The inspector noted that the procedure was incomplete and signed by the previous LD on 9/10/21. The inspector inquired regarding the missing LD approval and the missing step by step performance instructions. The clinical coordinator stated on 9/5/24 at 10:30 AM, "I will have our new director to update this procedure and to sign and date it." 3. An exit interview with the clinical coordinator on 9/5/24 at 12 noon confirmed the above findings.