

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D1030241	(X3) Date Survey Completed 11/13/2025
Name of Provider or Supplier Pinnacle Dermatology	Street Address, City, State 1124 Essington Rd, Joliet, IL	
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
D5407	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, lack of documentation, and interview with testing personnel (TP) #4; the laboratory failed to have one of one procedure for Potassium Hydroxide (KOH) preparations approved, signed, and dated by the current laboratory director. Findings include: 1. Review of laboratory policy and procedure manuals revealed no laboratory director approval, including signature and date, by the current laboratory director on the procedure titled, "Potassium Hydroxide (KOH)". 2. Interview with TP #4 on 11/13/2025, at 11:32 am, confirmed the laboratory failed to have the KOH procedure approved, signed, and dated by the current laboratory director.</p>
D5805	<p>TEST REPORT CFR(s): 493.1291(c)</p> <p>(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.</p>

This STANDARD is not met as evidenced by:

Based on review of laboratory records and interview with testing personnel (TP) #4; the laboratory failed to include all the required components of a laboratory test report for two of three patient test reports reviewed for Potassium Hydroxide (KOH) preparations. Findings Include: 1. Review of two of three patient test reports (MRN: A572216, MM0000818272) for KOH testing found the laboratory failed to indicate the test performed and the test result /interpretation, on the laboratory's test report. 2. On survey date 10-01-24, at 11:32 pm, TP #4 confirmed two patient test reports failed to identify the test performed and the test result/interpretation on the patient test reports.