

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  14D2139348	<b>(X3) Date Survey Completed</b>  02/06/2018
<b>Name of Provider or Supplier</b>  Pinnacle Dermatology	<b>Street Address, City, State</b>  2500 S Highland Ave Suite 320, Lombard, IL	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5805</b>	<p><b>TEST REPORT</b> CFR(s): 493.1291(c)</p> <p>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> <p>This STANDARD is not met as evidenced by: Based on review of patients test reports and interview with the laboratory director, the test report did not indicate the following: *The name and address of the laboratory location where the test was performed. Findings: 1. The surveyor selected 5 patients' test reports for review. The name and address of the laboratory location where the test was performed was not indicated on 5 of 5 patients' test reports reviewed. 2. During survey date 02/06/18, the laboratory director confirmed the surveyor's findings.</p>
<b>D6102</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1445(e)(12)</p> <p>The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.</p>

This STANDARD is not met as evidenced by:  
 Based on review and interview, the laboratory director failed to ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably. Findings: 1. Review of Laboratory Personnel Report (FORM CMS 209), signed by the laboratory director, and dated 02/06/2018, revealed that there were 3 persons listed as high complexity testing personnel who perform histopathology procedures and 3 persons listed as moderate complexity testing who perform Potassium Hydroxide (KOH) wet mount procedures. 2. Review of personnel records revealed that there was no documentation to show the highest level of education (degree, diploma, or transcript) for 1 of 3 persons performing high complexity, and 3 of 3 persons performing moderate complexity testing. 3. During survey date 02/06/18, the laboratory director confirmed the surveyor's findings.

**D6107**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
 CFR(s): 493.1445(e)(15)

The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:  
 Based on review policies and procedures and laboratory records and interview, the laboratory director failed to specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of all testing, that identifies which examinations and procedures each individual is authorized to perform. Findings: 1. Review of the laboratory's policies and procedures revealed that the laboratory performed histopathology and potassium hydroxide (KOH) procedures. There was no documentation to show that the laboratory director specified in writing which individuals fulfilled the duties and responsibilities of the following positions: a. Laboratory Director b. Clinical Consultant c. Technical Supervisor d. General Supervisor e. High Complexity Testing Personnel (Histopathology) f. Moderate Complexity Testing Personnel (KOH) 2. Review of 6 laboratory personnel listed on Laboratory Personnel Report (FORM CMS 209) revealed that there was no documentation to show that the laboratory director assigned their duties and responsibilities, as well as which tests each individual is authorized to perform for 6 of 6 laboratory personnel. 3. During survey date 02/06/18, the laboratory director confirmed the surveyor's findings.

**D6120**

**TECHNICAL SUPERVISOR RESPONSIBILITIES**  
 CFR(s): 493.1451(b)(7)(8)

(7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly,

accurately and proficiently.

This STANDARD is not met as evidenced by:

Based on review of personnel records and interview, the technical supervisor failed to be responsible for training and evaluating testing personnel. Findings: 1. Review of personnel records of persons listed as testing personnel on the Laboratory Personnel Report (FORM CMS 209) revealed that there was no documentation to show that testing personnel were trained and their competency assessed for 5 of 6 testing personnel who perform histopathology and potassium hydroxide (KOH) procedures. 2. During survey date 02/06/18, the laboratory director confirmed the surveyor's findings.