

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  15D0948583	<b>(X3) Date Survey Completed</b>  01/09/2018
<b>Name of Provider or Supplier</b>  Applegarth Dermatology Pc	<b>Street Address, City, State</b>  1861 South Sturdy Road, Valparaiso, IN	
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>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> <p>This STANDARD is not met as evidenced by: Based on document review and interview, the laboratory director failed to ensure testing personnel (TP) received training to perform histopathology grossing for two of two TP reviewed, and received training to read potassium hydroxide (KOH) slides prior to testing patients' specimens for one of two TP reviewed. Findings include: 1. Review of "Laboratory Personnel Report (CLIA)" form (CMS-209), signed by the Laboratory Director on 1-4-2018, indicated SP#3 and SP#4 were testing personnel. 2. Review of patient test reports indicated the following: a. SP#3 performed KOH testing for patients #3 (4-25-2017), #4 (4-4-2017), and #12 (11-30-2017). b. SP#3 performed grossing for patients #9 (9-13-2017) and #11 (12-7-2017). c. SP#4 performed grossing for patients #8 (10-12-2017) and #10 (12-19-2017). 3. Review of policy / procedure titled: "Quality Assurance Manual," approved by the laboratory director on 1-3-2017, read: "All laboratory personal are trained properly commensurate with their positions, duties, and responsibilities." 4. In interview on 1-9-2018 at 10:57 AM, SP#1 acknowledged SP#3 and SP#4 perform KOH and grossing on patient specimens and indicated SP#3 was not trained to read KOH slides. SP#1 further indicated SP#3 and SP#4 were not trained to perform grossing.</p>
<b>D6103</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1445(e)(13)</p>

The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills.

This STANDARD is not met as evidenced by:

Based on document review and interview, the laboratory director failed to establish policies and procedures for the competency of two of two testing personnel reviewed. Findings include: 1. Review of "Laboratory Personnel Report (CLIA)" form (CMS-209), signed by the Laboratory Director on 1-4-2018, indicated SP#3 and SP#4 were testing personnel. 2. Review of patient test reports indicated the following: a. SP#3 performed potassium hydroxide (KOH) testing for patients #3 (4-25-2017), #4 (4-4-2017), and #12 (11-30-2017). b. SP#3 performed grossing for patients #9 (9-13-2017) and #11 (12-7-2017). c. SP#4 performed grossing for patients #8 (10-12-2017) and #10 (12-19-2017). 3. In interview on 1-9-2018 at 10:57 AM, SP#1 acknowledged SP#3 and SP#4 performed KOH and grossing on patient specimens and indicated the laboratory did not have competency policies / procedures and did not perform competency for KOH testing and grossing for SP#3. SP#1 further indicated the laboratory did not perform competency for grossing for SP#4.