

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 15D0948583	(X3) Date Survey Completed 12/20/2021
Name of Provider or Supplier Applegarth Dermatology Pc	Street Address, City, State 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.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on observation, record review, and interview, two of seven solutions (XS-3 Xylene Substitute and High-Def Acid Rinse) for hematoxylin and eosin staining were used past the expiration date (April 2020 and November 2019 respectively) for eight of nine patients (PT#1 to PT #8) reviewed. Findings include: 1. On 12/20/21 at 11:23 am, a staining solution (XS-3 Xylene Substitute lot 065718) was observed to have an expiration date of 4/2020 and there was no date included on the bottle to indicate when it was opened and used for patient testing. 2. On 12/20/21 at 11:30 am, a second staining solution (High-Def Acid Rinse lot 050283) was observed to have an expiration date of 11/2019 and there was no date included on the bottle to indicate when it was opened and used for patient testing. 3. Review of nine medical records indicated that the samples from PT#1 through PT#8 for hematoxylin and eosin staining had been cleared with the XS-3 Xylene Substitute lot 065718 and stained with the High-Def Acid Rinse lot 050283. PT#1 on 10/21/2020 PT#2 on 11/10/2020 PT#3 on 12/2/2020 PT#4 on 1/27/2021 PT#5 on 2/3/2021 PT#6 on 3/8/2021 PT#7 on 9/25/2020 PT#8 on 8/20/2021 4. On 12/20/21 at 3:20 pm, SP1 confirmed that the XS-3 Xylene Substitute lot 065718 and the High-Def Acid Rinse lot 050283 were expired and would need to be replaced as soon as possible. 5. The annual test volume for histopathology testing is approximately 4032.</p>