

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D2135089	(X3) Date Survey Completed 11/09/2021
Name of Provider or Supplier Pshmg Camp Hill Dermatology	Street Address, City, State 425 N 21st Street, Camp Hill, PA	
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
D5449	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on review of Potassium Hydroxide (KOH) quality control (QC) records and interview with Technical Consultant (TC) #4, the laboratory failed to document a negative and positive control material, each day of patient testing for KOH microscopic examinations for 2020 and 2021 Findings Include: 1. On the day of survey, 11/09/2021 at 09:20 a.m., reviewed of the KOH microscopic examinations QC records, revealed the laboratory did not document a negative and positive control materials each day of patient testing for the following: 2020: - 5 of 5 days of patient testing in November. - 1 of 2 days of patient testing in December. 2021: - 3 of 3 days of patient testing in January - 5 of 5 days of patient testing in September. 2. The TC#4 confirmed the findings above on 11/09/2021 around 11:25 a.m.</p>
D5601	<p>HISTOPATHOLOGY CFR(s): 493.1273(a)(f)</p> <p>(a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (f) The laboratory must document all control procedures performed, as specified in this section.</p>

This STANDARD is not met as evidenced by:

Based on review of quality control (QC) slide evaluation records and interview with the Laboratory Director (LD), the laboratory failed to document a positive and negative reactivity every day of patient testing for Immunohistochemical (IHC) stains performed in 2019, 2020, and 2021. Findings include: 1. On the day of survey 11/09/2021 at 10:25 a.m., review of IHC Staining records revealed, IHC positive and negative controls were not documented in 2019, 2020 and 2021 2. The LD confirmed the finding above on 11/09/2021 around 11:30 a.m.