

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  24D0677251	<b>(X3) Date Survey Completed</b>  06/14/2022
<b>Name of Provider or Supplier</b>  Associated Skin Care Specialists Pa-Fridley	<b>Street Address, City, State</b>  500 Osborne Rd Ne Suite #330, Fridley, MN	
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>D2015</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by:  . Based on document review and interview with laboratory personnel, the laboratory failed to retain testing accuracy verification records for three of three microscopic examinations performed in 2021 for at least two years. Findings are as follows: 1. The laboratory performed microscopic examinations for fungus, parasites, and viruses under the specialty of Microbiology as confirmed by the Histotechnician (HT) during a tour of the laboratory at 10:35 a.m. on 06/14/22. 2. Requirements for twice annual verification of accuracy testing for KOH fungal preparations (K), Scabies parasite preparations (S), and Tzanck virus preparations (T) were established in the laboratory's Proficiency Testing for Provider Performed Microscopic Examinations procedure found in the KOH, Tzanck, Scabies manual. 3. One verification of testing accuracy document for Tzanck preparations was found during review of 2021 laboratory records. The laboratory was unable to provide a second accuracy verification from 2021 for Tzanck preparations upon request. 4. Verification of testing accuracy documents for KOH and Scabies preparations were not found during review of 2021 laboratory records. The laboratory was unable to provide testing accuracy</p>

verification documents from 2021 for KOH and Scabies preparations upon request. 5. The laboratory's KOH and Tzanck test logs indicated patient samples received microscopic examinations for fungus and viruses in 2021. The Scabies test log indicated no patient testing for parasites occurred in 2021. See below. 2021 Test Number of patients K 13 S 0 T 1 6. In an interview at 11:40 a.m. on 06/14/22, the HT confirmed the above finding. The HT indicated verification of microscopic examination accuracy had been performed in 2021 per information obtained from the providers, but the documents could not be found.