

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D0418678	(X3) Date Survey Completed 03/24/2022
Name of Provider or Supplier Dermatology Associates	Street Address, City, State 18425 W Creek Dr, Ste F, Tinley Park, IL	
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
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on record review, and interview, the laboratory failed to ensure three of five testing personnel (TP) who routinely perform Potassium Hydroxide (KOH) preparations, participate in six PT events (2020, 2021) reviewed. Findings include: 1. The Mycology PT records for 2020 through 2021, the Laboratory Personnel Report (CMS-209), employee files, and laboratory's PT policy were reviewed. 2. The PT policy reviewed required PT samples to be tested by testing personnel (TP) who routinely perform the test in the laboratory. 3. The CMS-209 and employee files revealed five laboratory personnel (TP1, TP2, TP3, TP4, and TP5) listed and authorized to perform KOH preparations. 4. The KOH slide preps PT documents showed that the laboratory participated in six PT sample testing events during the years of 2020 and 2021. 5. Further review of the PT documents showed TP2, TP4, and TP5 had failed to participate in any PT sample testing event during the period reviewed. 6. The laboratory director confirmed the above findings on 03/24/2022 12: 50 PM.</p>
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p>

This STANDARD is not met as evidenced by:

Based on record review, lack of documentation, and interview, the laboratory failed to verify the accuracy of the Histopathology slide interpretations (2020, 2021) affecting 1500 reported patients' results. Findings include: 1. The laboratory's quality assurance (QA) documents for the years of 2020 and 2021, the Laboratory Personnel Report (CMS-209), personnel records, and manual were reviewed. 2. Interview with the laboratory manager on 03/24/2022 at 11:10 AM, stated that Histopathology slide interpretations are read at the facility. 3. The CMS-209 and personnel records revealed two testing personnel (TP1 and TP2) listed and authorized to read or interpret tissue slides in the laboratory. 4. The QA policy and procedures and documents reviewed failed to include a process to ensure the continued accuracy of the TP reading Histopathology slides during the period reviewed. 5. The laboratory reported 1500 Histopathology results during the year of 2021. 6. The laboratory director and manager confirmed the above findings on 03/24/2022 12:50 PM.