

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D0957471	(X3) Date Survey Completed 09/01/2020
Name of Provider or Supplier Dermatology Consultants, Pa	Street Address, City, State 576 Bielenberg Drive Suite #200, Woodbury, MN	
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
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> <p>This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory failed to perform and document activities used to verify the accuracy of 1 of 2 Microbiology microscopic examinations at least twice annually in 2018 and 2019. Findings are as follows: 1. The laboratory performed parasitic (Scabies) microscopic examinations under the specialty of Microbiology as confirmed by the Clinic Manager (CM) during a tour of the laboratory at 1:15 p.m. on 09/01/20. 2. Documentation of the Scabies twice annual verification of accuracy was not found for 2018 and 2019 during review of laboratory records. The laboratory was unable to provide the verification documentation upon request. 3. Laboratory records indicated seven patients received Scabies testing in 2018 and four patients received Scabies testing in 2019. 4. In an interview at 2:20 p.m. on 09/01/20, the CM confirmed the above finding. .</p>
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 document review and interview with laboratory personnel, the laboratory</p>

failed to ensure a solution used for Microbiology microscopic examinations was not used after the expiration date had been exceeded in 2018 and 2019. Findings are as follows: 1. The laboratory performed fungal microscopic examinations under the Microbiology specialty as confirmed by the Clinic Manager (CM) during a tour of the laboratory at 1:15 p.m. on 09/01/20. 2. Expired Chlorazol Black solution was used for testing patient specimens in 2018 and 2019 as indicated on the KOH/Stain Reagent Log provided by the laboratory. See below for detailed information. Solution Exp. Dates used Chlorazol Black 9/15/18 09/16/18 - 12/31/19 3. The laboratory performed approximately 90 fungal microscopic examinations annually as indicated on the Form CMS-116 CLIA Application for Certification. 4. In an interview at 2:35 p.m. on 09/01/20, the CM confirmed the above finding.