Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D1088081	02/21/2025
Name of Provider or Supplier	**Street Address, City, State**	
Duly Health And Care Hinsdale Derm	40 S Clay St, Ste Ll30, Hinsdale, 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	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) (b)(1) 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. This STANDARD is not met as evidenced by: a) Based on review of laboratory policies and procedures, the CMS-209 (Laboratory Personnel Report) Form, American Proficiency Institute (API) proficiency testing (PT) records, and interviews with laboratory representatives (LR), the laboratory failed to ensure all testing personnel (TP) who routinely perform microscopic potassium hydroxide (KOH) testing in the subspecialty of mycology participated in six of six PT events reviewed. Findings include: 1) Review of laboratory policies and procedures revealed the policy, "Derm Lab Quality Assessment Policy", which stated, under "Policy", "6. Each Physician and Mid-Level Practitioner will participate in the rotation for proficiency testing per the Proficiency Testing Policy." 2) Review of laboratory policies and procedures revealed the policy, "Derm Lab Proficiency Testing Policy", which stated, under "1. KOH Proficiency Testing", "The providers will rotate so that every test event will be completed by a different provider." 3) Review of the CMS-209 (Laboratory Personnel Report) Form revealed four TP (TP #1-4) performing microscopic KOH testing. 4) Review of API PT records for microscopic KOH testing in 2023 and 2024 found that three of four TP listed on CMS-209 had not participated in microscopic KOH challenges. Event: Year: TP: 1 2023 1 2 2023 1 3 2023 1 1 2024 1 2 2024 1 3 2024 1 5) Interviews with LR #1 and LR #2 on 02/21/2025, at 12:34 pm, confirmed the laboratory failed to ensure all TP who routinely perform microscopic KOH testing participated in six of six PT events reviewed. b) Based on review of laboratory policies and procedures, the CMS-209 (Laboratory Personnel Report) Form, College of American Pathologists (CAP) proficiency testing (PT) records, and interviews with laboratory representatives (LR),

	the laboratory failed to ensure all testing personnel (TP) who routinely perform microscopic scabies testing in the subspecialty of parasitology participated in five of five PT events reviewed. Findings include: 1) Review of laboratory policies and procedures revealed the policy, "Derm Lab Quality Assessment Policy", which stated, under "Policy", "6. Each Physician and Mid-Level Practitioner will participate in the rotation for proficiency testing per the Proficiency Testing Policy." 2) Review of laboratory policies and procedures revealed the policy, "Derm Lab Proficiency Testing Policy", which stated, under "2. Scabies Proficiency Testing", "The providers will rotate so that every test event will be completed by a different provider." 3) Review of the CMS-209 (Laboratory Personnel Report) Form revealed four TP (TP #1-4) performing microscopic scabies testing. 4) Review of CAP PT records for microscopic scabies testing in 2023 through the survey date of 02/21/2025 found that three of four TP listed on the CMS-209 had not participated in microscopic scabies challenges. Event: Year: TP: 1 2023 2 2 2023 2 1 2024 2 2 2024 2 1 2025 2 5) Interviews with LR #1 and LR #2 on 02/21/2025, at 12:34 pm, confirmed the laboratory failed to ensure all TP who routinely perform microscopic scabies testing participated in five of five PT events reviewed.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records, lack of documentation, and interviews with laboratory representatives (LR), the laboratory failed to evaluate results of bi-annual method accuracy (proficiency testing/peer reviewed histopathology interpretations) for eight of eight events in 2023 and 2024 in the subspecialty of histopathology. Findings include: 1) Review of laboratory policies and procedures revealed the policy, " Derm Lab Proficiency Testing Policy", which stated, a) Under "Policy", "Personnel will rotate completing the proficiency but review the results of each event." b) Under "1. [Histopathology] Proficiency Testing (Slide Review) ....Histologic Interpretation Criteria", "The interpretation of the slides in evaluated ...." 2) Review of laboratory records revealed a lack of documentation of evaluations of results upon receipt of peer reviewed histopathology interpretations for eight of eight reviewed bi-annual method accuracy events. Year: Event: 2023 Q1 2023 Q2 2023 Q3 2023 Q4 2024 Q1 2024 Q2 2024 Q3 2024 Q4 3) Interviews with LR #1 and LR #2 on 02/21/2025, at 09:45 am, confirmed laboratory failed to evaluate results of bi-annual method accuracy (proficiency testing/peer reviewed histopathology interpretations) for eight of eight events in 2023 and 2024.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) (d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, lack of documentation, and interviews with laboratory representatives (LR), the laboratory failed to have policy and procedure manuals reviewed, approved, signed, and dated by the laboratory

	director (LD), as noted on the CMS-209 (Laboratory Personnel Report) Form, for four of four standard operating procedures in the subspecialty of histopathology. Findings include: 1) Review of laboratory policies and procedures revealed no LD approval, including signature and date, by the LD for four of four histopathology standard operating procedures: a. "Specimen Collection, Handling and Transport Guidelines", b. "Quality Assurance Plan", c. "Transferring Laboratory Materials for Consultation and Continuity of Care", d. "Results Reporting" 2) Interviews with LR #1 and LR #2 on 02/21/2025, at 11:03 am, confirmed laboratory failed to have policy and procedure manuals reviewed, approved, signed, and dated by the laboratory director (LD) in the subspecialty of histopathology.