Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D2028816	(X3) Date Survey Completed 07/22/2025
Name of Provider or Supplier Dermatology And Skin Cancer Consultants, Pllc	**Street Address, City, State** 701 Medical Park Drive, Humboldt, TN	
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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on laboratory observation, lack of documentation, procedure manual review, review of patient accessioning logs, and staff interviews, the laboratory failed to perform competency assessments for scabies examinations for three of three testing personnel in 2024 and 2025. The findings include: 1. Laboratory observation on 07/22/25 at 8:15 a.m. revealed a microscope used for reading histopathology slides and examining skin scrapings for fungal elements and scabies. 2. Scabies competency assessment for testing persons two, three, and four was not documented in 2024 and 2025. 3. A review of the laboratory procedure manual revealed the following statement under section 10. 3. "Twice a year, the Laboratory Director will observe all testing personnel performing a KOH prep for accuracy in technique and specimen collection." Under section XIV-"SCABIES SKIN SCRAPING PROCEDURE," the following was noted: "Competency protocol for scabies preps is the same as for KOH preps above." 4. A review of patient accessioning logs revealed that four scabies exams were performed since the last survey date of 04/02/2024, for patient number 12500 on 01/07/25, patient number 38741 on 01/14/25, and patient number 2026 on 07/01/25 on two separate sites. Testing person three performed all four scabies examinations. 5. The laboratory director confirmed the survey findings during an interview on 07/22/25 at 12:00 p.m. Work Key: KOH=Potassium Hydroxide
D5219	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(2)

	(c)(2) Any test or procedure listed in subpart I of this part for which compatible proficiency testing samples are not offered by a CMS-approved proficiency testing program. This STANDARD is not met as evidenced by: Based on laboratory observation, a review of the laboratory procedure manual, a review of patient test reports, lack of documentation, and staff interview, the laboratory failed to verify the accuracy of scabies examination twice a year in 2025, with three patients tested. The findings include: 1. Laboratory observation on 07/22/25 at 8:15 a.m. revealed a microscope used for reading histopathology slides and examining skin scrapings for fungal elements and scabies. 2. A review of the laboratory procedure manual revealed that accuracy for scabies is determined by the laboratory director reviewing a captured photo maintained in the patient chart to determine agreement with the original interpretation. 3. A review of patient test reports revealed that four scabies exams were performed in 2025 for patient number 12500 on 01/07/25, patient number 38741 on 01/14/25, and patient number 2026 on 07/01/25 (two separate sites). None of the four had captured images maintained as part of the patient chart. 4. The laboratory director had not documented a second review of the examinations, resulting in the laboratory failing to verify the accuracy of the scabies exam twice a year in 2025. 5. The laboratory director confirmed the survey findings during an interview on 07/22/25 at 12:00 p.m.
D6051	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(v) (b)(8)(v) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and This STANDARD is not met as evidenced by: Based on laboratory observation, review of testing personnel competency assessments, and staff interviews, the technical consultant failed to include blind testing as part of the Potassium Hydroxide (KOH) fungal detection competency assessment documentation in 2024 and 2025 for six of six competency assessments reviewed for three of three testing personnel. The findings include: 1. Laboratory observation on 07/22/25 at 8:15 a.m. revealed a microscope used for reading histopathology slides and examining skin scrapings for fungal elements and scabies. 2. A review of testing personnel KOH competency assessments revealed that six of six KOH competency assessments performed for testing persons two, three, and four in 2024 and 2025 did not include documentation of blind testing assessment. 3. The laboratory director confirmed the survey findings during an interview on 07/22/25 at 12:00 p.m.