Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D2115152	11/13/2025
Name of Provider or Supplier	**Street Address, City, State**	
Southern Sierra Specialty Lab	105 E Sydnor, Ste 100, Ridgecrest, CA	

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	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) 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. This STANDARD is not met as evidenced by: Based on the surveyor's review of the laboratory's policy and procedure, randomly chosen patient records, lack of proficiency testing records, and an interview with the office manager (OM), director of operations (DO) and resource lead (RL), it was determined that the laboratory failed to verify the accuracy of any test or procedure performed at least twice annually for Dermatopathology and Mycology for the laboratory director (LD) as the testing personnel. The findings include: 1. The laboratory failed to follow their policy which specified that two cases every six months will be selected to be sent for proficiency testing records for the years 2024 and 2025 for the Dermatopathology subspecialty. There was no available policy for Mycology, specifically for potassium hydroxide (KOH) testing on the day of the survey. 2. A total of eight Dermatopathology patient records were randomly selected on the November 13, 2025 survey. This selection included two records from each year, covering the period from 2022 to 2025. At the time of the survey, there were no proficiency testing records available for the LD, which affected four out of the eight records, specifically: a. M24-022 b. M24-083 c. M25-005 d. M25-079 3. Another set of patient records were reviewed by the surveyor for KOH testing and it was determined that no proficiency testing records were performed for the LD for the years 2022, 2023, 2024, and 2025. This affected all eight patient records selected, which included: a. Patient CR, examined on 5/13/2022 b. Patient DS, examined on 5 /25/2022 c. Patient BP, examined on 2/3/2023 d. Patient DM, examined on 3/29/2023 e. Patient ER, examined on 3/01/2024 f. Patient SA, examined on 9/25/2024 g. Patient RB, examined on 1/15/2025 h. Patient TP, examined on 11/5/2025 4. The reliability and accuracy of patient tests reported cannot be assured. 5. The OM, DO and RL

	affirmed by interviews on November 13, 2025, at approximately 9:30 a.m., that the laboratory lacked proficiency testing records for the LD in the years 2024 and 2025 for Dermatopathology and KOH for the years 2022, 2023, 2024, and 2025 as mentioned in the prior statements. 6. The laboratory's testing declaration form (Lab-144) submitted at the time of the survey stated that approximately 100 Dermatopathology and 18 KOH patient test samples were performed annually including the time when proficiency testing records were missed for the LD.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on the lack of policy and procedure and interviews with the office manager (OM), director of operations (DO) and resource lead (RL), it was determined that the laboratory failed to have an established and approved written procedure for the potassium hydroxide (KOH) testing. The findings include: 1. The surveyor's review of the laboratory's policy and procedure binder indicated that there was no established and approved written procedure for KOH testing. 2. In interviews conducted on November 13, 2025, at approximately 10:10 a.m., the OM, DO, and RL confirmed that the laboratory did not have an established and approved policy and procedure for KOH testing for staff to follow to ensure compliance. 3. The testing declaration form submitted at the time of the survey stated that approximately 18 KOH patient test samples were performed annually, including the time when the laboratory lacked an established and approved written policy for KOH testing.
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 the interviews with the office manager (OM), director of operations (DO) and resource lead (RL), review of the laboratory's policies and procedures, and document control on November 13, 2025; it was determined that the laboratory failed to follow an established policy and procedure that was approved, signed, and dated by the current laboratory director. The findings include: 1. The surveyor's review of the policy and procedure's document control page showed that the laboratory failed to follow their policy for the current laboratory director to review and sign annually since its established date. 2. On November 13, 2025, at approximately 9:40 a.m., the OM, DO and RL affirmed by interviews that the all of the document control pages for each policy and procedure for the laboratory operations and testing were not approved, signed, and/or dated by the current laboratory director. 3. The testing declaration form (Lab-144) submitted at the time of survey showed that the laboratory performed and reported approximately 100 patient samples for Dermatopathology and 18 patient samples for potassium hydroxide testing annually during the time when

	policies and procedures were not approved, signed, and/or dated by the current laboratory director.
D5485	CONTROL PROCEDURES CFR(s): 493.1256(h) (h) If control materials are not available, the laboratory must have an alternative mechanism to detect immediate errors and monitor test system performance over time. The performance of alternative control procedures must be documented. (a) The laboratory must check the following for positive and negative reactivity using control organisms: This STANDARD is not met as evidenced by: Based on the lack of the potassium hydroxide (KOH) policy and procedure, patient test records, and interviews with the office manager (OM), director of operations (DO) and resource lead (RL), it was determined that the laboratory failed to document the performance of an alternative control procedures. The findings include: 1. The laboratory's practice was to document each patient examined for KOH testing in a log book. However, it lacked to specify if an alternative control procedure was performed to meet quality control requirement thereby affecting eight randomly chosen patient records reviewed. 2. The laboratory lacked a policy and procedure for KOH testing thereby potentially affecting the performance of an alternative quality control. 3. The quality and reliability of patient test results reported cannot be assured. 4. According to the testing declaration form (Lab-144) submitted on November 13, 2025, the laboratory performed and reported approximately 18 patient samples for KOH testing annually during the time when no alternative quality control procedures were established nor performed for the years 2022, 2023, 2024, and 2025. .
D6082	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1) (e) The laboratory director must-- (e)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing; This STANDARD is not met as evidenced by: Based on the surveyor's review of the laboratory's policies and procedures, errors found during record review and interviews with the office manager, director of operations and resource lead on November 13, 2025, the laboratory director is herein cited for failure to provide quality laboratory services for all aspects of testing especially in the preanalytic phase of testing. The findings include: 1. The laboratory lacked a policy and procedure for potassium hydroxide testing. See D5401 2. The laboratory director failed to approved, signed, and/or dated the document control page of each policy and procedure annually. See D5407. .
D6089	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(i) (e)(4)(i) The proficiency testing samples are tested as required under subpart H of this part;

	This STANDARD is not met as evidenced by: Based on surveyor's review of patient test reports, lack of proficiency testing (PT) records, and interviews with the office manager, director of operations and resource lead on November 13, 2025; it was determined that the laboratory director failed to ensure that the proficiency testing was performed as required under subpart H of this part. The findings include: 1. The laboratory lacked PT records for the Dermatopathology subspecialty for the years 2024 and 2025. Additionally, PT records for the Mycology subspecialty were missing from 2022 to 2025. See D5217. .
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur; This STANDARD is not met as evidenced by: Based on the lack of the laboratory's policy and procedure, randomly selected patient test records and interviews with the office manager, director of operations and resource lead on November 13, 2025; the laboratory director is herein cited due to failure to ensure that an alternative quality control was performed. The findings include: 1. The laboratory failed to perform and document an alternative quality control for the potassium hydroxide testing. See D5485.