Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 10D1016275	**(X3) Date Survey Completed** 07/31/2024
Name of Provider or Supplier Emily F Arsenault Md Pa	**Street Address, City, State** 8926 77th Ter E Ste 101, Bradenton, FL	
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**
D0000	An announced CLIA recertification survey was conducted at Emily F Arsenault MD PA dba Arsenault Dermatology on 07/31/2024. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
D2044	MYCOLOGY CFR(s): 493.827(d) (1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) Remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on review of MLE (Medical Laboratory Evaluation) proficiency testing documentation and interview with the Laboratory Manager, the laboratory failed to take remedial action for one (M2 2024) out of two proficiency testing events (M1 and M2 2024) reviewed with an unsatisfactory score for 2 out of 2 years (2023-2024) reviewed. Findings included: Review of the MLE proficiency testing revealed that the laboratory failed to evaluate the proficiency testing results for M2 Nonchemistry (KOH slides) with a score of 0. Interview on 07/31/2024 at 4:30 PM with the Laboratory Director confirmed she had not performed remedial action and was unaware of the score of 0 on the M2 Nonchemistry (KOH slides) proficiency testing dated 5/14/2024.
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 review of MLE (Medical Laboratory Evaluation) proficiency testing documentation and interview with the Laboratory Manager, the laboratory failed to evaluate two proficiency testing events (M2 2023 and M2 2024) out of three proficiency testing events reviewed (M2 2023, M1 2024, and M2 2024) for 2 out of 2 years (2023-2024) reviewed. Findings included: Review of the MLE proficiency testing revealed that the laboratory failed to evaluate the proficiency testing results for M2 2023 and M2 2024 for both Nonchemistry (KOH slides) and Chemistry (Scabies Detection and Pinworm Prep). Interview on 07/31/2024 at 4:30 PM with the Laboratory Director confirmed the M2 2023 and M2 2024 proficiency testing results were not reviewed. She stated she did not know she had to evaluate all proficiency testing records. This is a repeat deficiency.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on record review and interview with the Laboratory Director, the Technical Consultant failed to maintain annual competency records for four (#D, #E, #F and #G) of four individuals performing moderate complexity testing for 1 (2023) out of 2 years reviewed (2023-2024). Findings included: Review of the CMS 209, Laboratory Personnel Report, signed by the Laboratory Director and dated 07/31/2024 revealed the Laboratory Director was also the Technical Consultant. The CMS 209 showed the laboratory had four Testing Personnel (TP), #D, #E, #F, and #G, performed moderate complexity testing. Review of personnel records revealed TP #D (date of hire [DOH] 4 /18/2022), TP #E (DOH 7/15/2014), TP #F (DOH 7/1/21), and TP #G (DOH 8/5 /2013), had no competency records completed for 2023. On 07/31/24 at 4:00 PM, the Laboratory Director confirmed that competency was not completed annually for TP #D, #E, #F,and #G.