Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0989523	01/26/2026
Name of Provider or Supplier	**Street Address, City, State**	
Steven M Hacker Md Pa	230 George Bush Blvd Ste B, Delray Beach, 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 Steven H Hacker MD PA on 1/23-1/26/26. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories.
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 record review and interview, the laboratory failed to verify accuracy of histopathology testing twice annually in 2024 and 2025 for 2 out of 2 Testing Personnel. Findings: 1. Review of Laboratory Personnel Report indicated Testing Personnel A and Testing Personnel B were performing histopathology testing. 2. Review of Histopathology peer review testing revealed the following: a. Peer review testing was not completed for Testing Personnel A and Testing Personnel B twice annually in 2024 and reviewing pathologist was not labeled to indicate who it was. Proficiency testing was not completed for Testing Personnel A and Testing Personnel B twice annually in 2025 and reviewing pathologist was not labeled to indicate who it was. 3. Review of peer review testing policy for Mohs Surgery Slides read,"1. Will participate in one of either: Peer reviewed QC and Proficiency testing - randomly selected and submit 2 cases each quarter to be reviewed by peer reviewer (another dermatologist or Dermatopathologist) or participate in the ASMS Proficiency Annual Testing Program." 4. On 1/23/2026 at 4:36 PM, the Laboratory Director and Testing Personnel B confirmed there was no complete histopathology peer review testing twice annually in 2024 and 2025 for 2 out of 2 Testing Personnel.
D5601	HISTOPATHOLOGY CFR(s): 493.1273(a)(f)

	(a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to have positive and negative control slides for 2 out 2 patients tested for immunohistochemical stains. Findings: 1. Review of Patient reports and slides revealed the following: a. Patient 1 was tested for Cytokeratin (AE1 / AE3), Cluster of Differentiation 10 (CD10), and Epithelial Antigen (Ber-EP4) on 4/28/2025 with no positive and negative immunochemical control sides. b. Patient 2 was tested for SRY-box transcription factor 10 (SOX10) on 5/20/2024 with no positive and negative immunochemical control sides. 2. Review of Laboratory Quality Control of Slides: Histopathology signed by laboratory director on 9/25/2025 revealed there was no immunohistochemical quality control policy. 3. On 1/23/2026 at 4:36 PM, the Laboratory Director and Testing Personnel B confirmed no positive and negative control slides for 2 out 2 patients test for immunohistochemical stains.
D5805	TEST REPORT CFR(s): 493.1291(c) (c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to list the correct laboratory name and technical component location for 5 out of 5 patient reports reviewed. Findings: 1. Review of Patient reports revealed the following: Patient 1 was tested for Cytokeratin (AE1 / AE3), Cluster of Differentiation 10 (CD10), and Epithelial Antigen (Ber-EP4) on 4/28/2025. Patient 1's report listed the wrong lab name and technical component performed by another lab was not listed. b. Patient 2 was tested for SRY-box transcription factor 10 (SOX10) on 5/20/2024. Patient 2's report listed the wrong lab name and technical component performed by another lab was not listed. c. Patient 3 was tested for H&E on 6//17/2024. Patient 3's report listed the wrong lab name. d. Patient 4 was tested for H&E on 11/25/2024. Patient 4's report listed the wrong lab name. e. Patient 5 was tested for H&E on 1/13/2026. Patient 5's report listed the wrong lab name. 2. Review of Procedure manual revealed no policy for the requirement for patients reports. 3. On 1/23/2026 at 4:36 PM, the Laboratory Director and Testing Personnel B confirmed incorrect laboratory name and technical component location for 5 out of 5 patient reports reviewed.