Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0287270	06/30/2024
Name of Provider or Supplier	**Street Address, City, State**	
Joseph C Gretzula Do Faad Pa D/B/A	100 Ne 6th Street, Suite 106, Boynton 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	Recertification survey was conducted from 4/18/2024 to 6/30/2024. Joseph C Gretzula Do Faad PA D/B/A Boynton Beach Dermatology clinical laboratory was not in compliance with 42 CFR Part 493, requirements for clinical laboratories.
D5219	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(2) At least twice annually, the laboratory must verify the accuracy of 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 record review, and interview, the laboratory failed to perform twice annual Potassium Hydroxide (KOH) verification accuracy testing in 2023 for testing personnel F. Findings Included: Review of CMS -209 revealed employee F was testing personnel (TP). Review of the Quality Assurance/Peer Review policy issued on 11/1/22 revealed no procedure on how verification accuracy testing for KOH would be performed. Review of KOH patient logs revealed KOH was performed from 1/1/2023 to 1/1/2024. Review of KOH verification accuracy testing revealed no documentation of verification accuracy testing twice annually in 2023 for KOH for testing personnel F. On 4/18/2023 at 2:00 PM, the office staff stated proficiency testing was performed with another doctor and would be sent via email. No email was sent with the proficiency testing as requested.
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. (f) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on record review, and interview, the laboratory failed to have written positive and negative controls for immunohistochemical stains performed for 2 out of 3 patients reviewed for Histopathology testing, (patients #1 and #2). Finding included: Review of CMS -209 revealed testing personnel A, B and C were digital pathologist readers. Review of Surgical Pathology Reports revealed patient #1's specimen was collected on 3/21/2024 for SOX-10 (Melanoma IHC stain) and H&E (Hematoxylin and eosin stain) and reported on 3/31/2024. The controls were not documented for SOX-10. Patient #2's specimen was collected on 2/20/2024 for SOX-10 and H&E and reported on 3/31/2024. No written statement of address where slides were created and read digitally were documented. The controls were not documented for SOX-10. Review of Pathology Reports policy issued on 11/2/22 revealed no written Histopathology procedure for recording technical component (slide production) and professional component (slide reading and diagnoses) on surgical pathology reports. On 4/18/2023 at 3:01 PM, the laboratory Consultant confirmed the laboratory failed to have written positive and negative controls for immunohistochemical stains performed for 2 (patients 1 and 2) out of 3 patients reviewed for Histopathology testing.
D5805	TEST REPORT CFR(s): 493.1291(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 identify where technical and professional component was performed for 3 out of 3 patients reviewed for Histopathology testing, (patients #1, #2, #3). Finding included: Review of CMS -209 revealed testing personnel A, B and C were digital pathologist readers. Review of Surgical Pathology Reports revealed patient #1's specimen was collected on 3/21 /2024 for SOX-10 (Melanoma IHC stain) and H&E (Hematoxylin and eosin stain) and reported on 3/31/2024. There was no written statement of addresses where slides were created and read digitally. Patient #2's specimen was collected on 2/20/2024 for SOX-10 and H&E and reported on 3/31/2024. There was no documentation indicating the address where slides were created and read digitally. Patient #3's specimen was collected on 11/6/2023 for H&E and reported on 11/16/2023. There was no documentation of the address where slides were created and read digitally. Review of Pathology Reports policy issued on 11/2/22 revealed no written Histopathology procedure for recording technical component (slide production) and professional component (slide reading and diagnoses) on surgical pathology reports. On 4/18/2023

	at 3:00 PM, the Laboratory Consultant confirmed the laboratory failed to identify where technical and professional component was performed for 3 out of 3 patients reviewed for Histopathology testing.