Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2042478	01/31/2020
Name of Provider or Supplier	**Street Address, City, State**	
F Christopher Manlio Do Pa	903 N Central Ave, Kissimmee, 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	A Recertification survey was conducted on January 31, 2020. F Christopher Manlio DO PA clinical laboratory was not in compliance with 42 CFR 493, requirements for clinical 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 staff interview, the laboratory failed to verify the accuracy of the reading and interpretation of the Hematoxylin and Eosin (H&E) stain at least twice annually in 2019. Findings: The laboratory used peer review to verify the accuracy of the reading and interpretation H&E stains. Review of the laboratory's records showed that peer review for the Laboratory Director was only done once during 2019, on 6/25/19. During an interview on 1/31/19 at 2:28 PM, Mohs Technician A acknowledge that peer review was performed only once during 2019.
D5609	HISTOPATHOLOGY CFR(s): 493.1273(e)(f) (e) The laboratory must use acceptable terminology of a recognized system of disease nomenclature in reporting results. (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 staff interview, the laboratory failed to document and maintain a record of the open dates for reagents used in their Hematoxylin & Eosin

	(H&E) stains. Findings: Record review of the laboratory's Chemical Log showed that the laboratory failed to record when the reagents were opened from 1/31/18 to 1/31 /20. During an interview on 1/31/20 at 2:38 PM, Mohs Technician B confirmed they didn't record the open dates on their chemical log.
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 staff interview, the laboratory's final report failed to list the location where the technical and professional component was performed for 1 of 7 sampled patient reports examined (#7). Findings: Review of the histopathology final report for patient #7 showed that the name and address of the location where the technical and professional component were performed was not listed. During an interview on 1/31/20 at 3:07 AM, Mohs Technician B acknowledged that the histopathology final report did not have the name and address where the technical and professional component was performed for patient #7.