Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2062745	07/21/2021
Name of Provider or Supplier	**Street Address, City, State**	
Nosky Pa	512 Cypress Pkwy, 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 July 21, 2021. Nosky 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 2020. Findings: The laboratory used peer review to verify the accuracy of the readings and interpretation of H&E stains. Review of the laboratory's records showed that peer review for the Laboratory Director was not done in 2020. According to the Clinical Laboratory Improvement Amendments (CLIA) Application for Certification, signed and dated by the acting Laboratory Director on 02/20/2021, the laboratory's annual estimated histopathology test volume was 1,100 tests. On 07/21/2021 at 11:15 AM, Testing Personnel A stated it peer review for patient slides in 2020 was not performed until 2021.
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, patient test reports failed to provide all required information for laboratory test reports for 5 of 5 patients, (#1, #2, #3, #4, #5). Findings: Review of the patients' test reports showed the name on the report was the DBA (doing business as) name and not the name of the laboratory. According to the Clinical Laboratory Improvement Amendments (CLIA) Application for Certification, signed and dated by the acting Laboratory Director on 02/20/2021, the laboratory's annual estimated histopathology test volume was 1,100 tests. On 07/21/2021 at 12:30 PM, the Laboratory Director stated the name on the patient test reports was the DBA name.