Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2062745	06/22/2023
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 on June 22, 2023. Nosky PA clinical laboratory was not in compliance with 42 CFR 493, requirements for clinical laboratories.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on interviews and review of the procedure manual and the monthly Quality Assurance (QA) checklist, the laboratory failed to follow their procedures for monitoring, assessing and correcting identified problems from July 1, 2021 to June 22 2023. Findings: Review of the laboratory's procedure titled, Quality Management System - General Quality Assurance Plan noted, "The monthly quality assurance report will be reviewed with the appropriate personnel and maintained for 2 years with all other QC (Quality Control)/QA documentation." Review of the Monthly Quality Assurance Checklists showed the last time the form was filled out and signed by the Laboratory Director was 06/30/2021. On 06/22/2023 at 12:10 PM, the Practice Manager acknowledged the laboratory had not documented their QA.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for

	specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on interview and review of the procedure manual, the laboratory failed to include directions on labeling patient's Mohs Surgery slides from 06/26/2021 to 06/22/2023. Findings: Review of the procedure manuals showed the procedure manual was signed annually by the Laboratory Director on 06/26/2021, 06/21/2022 and 06/19/2023. Review of the procedure manual signoff pages noted, "A portion of this section of the laboratory manual has been modified from its original content, a brief explanation has been added in the comment section." The section for modifications made to the procedure manual was blank. Review of the procedure manual revealed the labeling method used by the laboratory for patient slides was not included in the manual. On 06/22/2023 at 12:17 PM, Testing Personnel B stated the directions for the way the laboratory labeled the patient slides was not included in the procedure manual.