Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2062745	10/08/2025
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	An announced CLIA recertification survey was conducted at Nosky PA on October 8, 2025. The laboratory is not in compliance with 42 CFR Part 493, Requirement for Laboratories. The following Conditions were cited: D5200 493.1230 - General Laboratory Systems D6076 493.1441 Condition: Laboratory Director
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: Based on observation, interview, review of laboratory procedure manual and safety data sheets, the laboratory failed to ensure protection from chemical hazards on 10/08 /2025. Findings: 1. During a tour of the laboratory on 10/08/2025 at 9:43 AM, the container of flammable waste was observed sitting next to the flammable cabinet. 2. Review of the policy tilted, Safety Policies, Procedures and Records noted, "Flammable chemicals will be stored in labeled flammable cabinet." 3. Review of the Safety Data Sheets for Eosin Y Solution 1% w/v in Alcohol, and 100% Reagent Alcohol read, "Store locked up." and "Store in an approved Flammable Liquid storage area." 4. During interview on 10/08/2025 at 9:5 AM, the Office Manager acknowledged the flammable waste container was not stored in the flammable cabinet.
D5200	GENERAL LABORATORY SYSTEMS CFR(s): 493.1230 Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, unless HHS approves

	a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of the procedure manual, record review, and interview, the laboratory failed to follow their procedures for monitoring, assessing and correcting identified problems from 07/01/2023 to 10/08/2025. (See D5291)
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 review of the procedure manual, record review, and interview, the laboratory failed to follow their procedures for monitoring, assessing and correcting identified problems from 07/01/2023 to 10/08/2025. This is a repeat deficiency from the survey performed on 06/22/2023 Findings: A. 1. Review of the Plan of Correction (POC) signed by the Laboratory Director on 08/22/2023, for the survey on 06/22/2025 noted, "The lab Director will be signing monthly reports for QA (Quality Assurance) going forward not just reviewing them without signature." The POC also indicated, "Monthly signature logs were added to section V of the Procedure manual by the Lab Director. Having signature reports will allow for monthly checks of such to ensure that they are being done and that the new process implemented as of July 1, 2023 will not be missed." 2. Review of the laboratory's procedure titled, Quality Management System - General Quality Assurance Plan showed, "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." 3. Review of the quality assurance checklists showed there were no checklist completed from 07/01/2023 to 03 /13/24. 4. During an interview on 10/08/2025, the Chief Executive Officer (CEO) stated there were no quality assurance checklists done in 2023 and the laboratory switched to doing a quarterly checklist in 2024. B 1. Review of the Quarterly Quality Assurance Checklist showed a checklist was completed for March 2024 and signed by the Laboratory Director, and the checklists for July 2024, November 2024, March 2025 and July 2025 were signed by Technical Supervisor A. Review of the checklists showed all statements were checked Yes or N/A (not applicable) 2. Review of the checklist showed the statements, "All required temperatures were taken and recorded" and "All instrument maintenance was performed and documented" were checked yes. Review of the laboratory's maintenance and function check logs showed not all the logs were completely filled out .(See D5435) 3. Review of the checklist showed the statements, "Quality control results were examined for possible problems. Review of the daily control slide showed that not all the stain quality was signed by the Mohs surgeon (See D5601) 4. During an interview on 10/08/2025 at 1:20 PM, the CEO acknowledged that some of the logs where not filled out completely. 5. During an interview on 10/08/2025 at 2:35 PM, the CEO acknowledged the quality assurance checklist was not effective in identifying missing documentation in the logs.

D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on observation, record review, and interview, the laboratory failed to use non-expired reagents in their Hematoxylin and Eosin stain for staining patient's histopathology slides on 09/18/2025. Findings: 1. During a tour of the laboratory on 10/08/2025 at 9:43 AM, two bottles of Hematoxylin Stain Solution Gill III were stored in the laboratory's flammable cabinet. Hematoxylin stain lot number 2324408 had an expiration date of 09/11/2025 and Hematoxylin stain lot number 250207 had an expiration date of 02/06/2027. Hematoxylin stain lot number 250207 had a received date of 09/25/2025 recorded on the bottle. 2. Review of the patient accession logs showed there were seven patients who had Mohs surgical procedures on 09/18/2025. 3. Review of the procedure titled, Quality Management Systems E. Analytical Quality Assurance Plan indicated, "All expired reagents, solutions, control materials and other supplies will be discarded and not used past the expiration date." 4. During an interview on 10/08/2025 at 9:52 AM, the Chief Executive Officer acknowledged the Hematoxylin stain expired on 09/11/2025 and the new bottle of Hematoxylin stain was not received until 09/25/2025, and patients' slides were stained on 09/18/2025 using the expired Hematoxylin stain.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) (b)(2)(i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (b)(2)(ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to document maintenance and function checks for 13 days (07/06/2023, 07/13/2023, 07/20/2023, 09/14/2023, 12/07/2023, 12/14/2023, 12/21/2023, 12/28/2023, 06/17/2024, 06/27/2024, 12/05/2024, 03/20/2025, 09/11/2025) that Mohs surgical procedures were performed from 13 months reviewed (7/2023, 9/2023, 11/2023, 12/2023, 1/2024, 4/2024, 6/2024, 8/2024, 12/2024, 1/2025, 3/2025, 4/2025, 9/2025). Findings: 1. The laboratory was used to record whether the reagents used in the H&E stain was changed, rotated, checked, or filtered on the Linear Stainer - Automated H / Eosin Reagent Log. Review of the Linear Stainer log showed it was not completed on 07/06/2023, 07/13/2023, 07/20/2023, 12/21/2023, 06/17/2024, and 09/11/2025. 2. The laboratory was used to record the daily cleaning of the microscope on the Microscope Maintenance Log. Review of the Microscope Maintenance Log showed the maintenance was not recorded on 07/06/2023, 07/13/2023, 07/20/2023, 09/14/2023, 06/17/2024, 06/27/2024, and 12/05/2024. 3. The laboratory was used to record the cleaning of the equipment, cleaning of all used surfaces, staining set up, daily checking of quality control logs, and cleanliness

	and organization of the laboratory on the Daily Laboratory Housekeeping Log. Review of the Housekeeping log showed the above mentioned duties with no initials that indicated duties were performed on 07/06/2023, 07/13/2023, 07/20/2023, 12/21 /2023, 06/17/2024, and 09/11/2025. 4. The Mohs Laboratory Equipment Maintenance Log was used to record the number of blocks, the temperature of the cryostat, the cryostat decontamination, the operation of the stainer conveyor, the operation of the stainer ventilation hood, and the laboratory room temperature and humidity. Review of the Equipment Maintenance log showed the above mentioned duties were not checked off as being done on 06/17/2024. 5. Review of the Mohs surgical accession logs showed there were 11 Mohs surgical procedure on 07/06/2023, 8 on 07/13/2023, 11 on 07/20/2023, 12 on 09/14/2023, 13 on 12/07/2023, 10 on 12/14/2023, 14 on 12 /21/2023, 12 on 12/28/2023, 1 on 06/17/2024, 13 on 06/27/2024, 14 on 12/05/2024,11 on 03/20/2025, and 9 on 09/11/2025, 6. During an interview on 10/08/2025 at 1:20 PM, the Chief Executive Officer acknowledged that some of the logs where no filled out completely.
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 review of the procedure manual, record review, and interview, the laboratory failed to document the acceptability of the Hematoxylin and Eosin (H&E) control slide for seven days (04/18/2024, 08/22/2024, 04/24/2025, 06/17/2024, 06/26 /2025, 07/24/2025, 09/04/2025) of the control log reviewed from 06/23/2023 to 10/08 /2025. Findings: 1. Review of the procedure manual titled IV. Testing Procedures B Mohs Micrographic Surgery 4. Staining stated, "Stain is checked daily for acceptable results by reading physician. The reading physician will complete the stain quality control sheet for each day of staining. 2. Review of Daily Cryotomy Slide / Stain Quality Control form showed the Mohs surgeon failed to document the acceptability of the H&E stain by signing the form on 04/18/2024, 08/22/2024, 04/24/2025, 06/26 /2025, 07/24/2025, and 09/04/2025. 3. Review of the Mohs surgical accession logs showed there were 12 Mohs surgical procedure on 04/18/2024, 15 on 08/22/2024, 12 on 04/24/2025, 1 on 06/17/2024, 10 on 06/26/2025, 13 on 07/24/2025, and 10 on 09 /04/2025. 4. Review of patient reports showed the Technical Supervisor performed the Mohs surgical procedures on 04/18/2024, 08/22/2024, 04/24/2025, and 06/26/2025, and the Laboratory Director performed the Mohs surgical procedures on 07/24/2025 and 09/04/2025. 5. During an interview on 10/08/2025 at 10:54 AM, the Chief Executive Officer acknowledged the stain quality control form was not signed by the Mohs surgeon for the above mentioned days.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.

	This CONDITION is not met as evidenced by: Based on review of the procedure manual, record review, and interview, the Laboratory Director failed to follow their procedures for monitoring, assessing and correcting identified problems from 07/01/2023 to 10/08/2025. (See D6093)
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur; This STANDARD is not met as evidenced by: Based on review of the procedure manual, record review, and interview, the Laboratory Director failed to follow their procedures for monitoring, assessing and correcting identified problems from 07/01/2023 to 10/08/2025. Findings: A 1. Review of the laboratory's Quality Assurance Checklist showed there were no checklists from 07/01/2023 to 03/13/2024. (See D5291) 2. During an interview on 10/08/2025, the Chief Executive Officer (CEO) stated there were no quality assurance checklists done in 2023 and the laboratory switched to doing a quarterly checklist in 2024. B 1. Review of the Laboratory's Quarterly Quality Assurance Checklist showed the checklist failed to identify missing documentation of maintenance and function check. (See D5291) 2. During an interview on 10/08/2025 at 1:20 PM, the CEO acknowledged that some of the logs were not filled out completely. 3. During an interview on 10/08/2025 at 2:35 PM, the CEO acknowledged the quality assurance checklist was not effective in identifying missing documentation in the logs.
D6123	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(iii) (b)(8)(iii) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records; This STANDARD is not met as evidenced by: Based on review of the procedure manual, record review, and interview, Technical Supervisor A failed to identify problems in the documentation of quality control and maintenance records from 07/18/2024 to 07 17/2025. Findings: 1. Review of the Quarterly Quality Assurance Checklist performed by Technical Supervisor A showed the checklist was not effective in identifying missing documentation in the logs. (See D5291) 2. During an interview on 10/08/2025 at 1:20 PM, the Chief Executive Officer (CEO) acknowledged some of the logs were not filled out completely. 3. During an interview on 10/08/2025 at 2:35 PM, the CEO acknowledged the quality assurance checklist was not effective in identifying missing documentation in the logs.