Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D1097477	01/16/2025
Name of Provider or Supplier	**Street Address, City, State**	
Carroll Dermatology Associates	826 Washington Road Ste 122, Westminster, MD	

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
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: Based on review of the procedure, test records, and physical slides and interview with the office manager (OM), the laboratory failed to have a procedure detailing the steps to take if a patient name was incorrect on a report and failed to correct the incorrect patient name on the physical slide stored in the laboratory. Findings: 1. The office sent biopsy material to an outside laboratory for slide processing. 2. The outside laboratory would send the slides and a final report template back to the office where the dermatopathologist would evaluate the slide and record the diagnosis on the report template. The slides were stored in the dermatopathologist's office. 3. If it was found that a slide and report contained an incorrect patient name, the outside laboratory would be notified to submit an updated report template, the dermatopathologist would record the diagnosis on the updated report, the office would record the incident on the "Quality Control for Dermatopathology Slides and Interpretation" log (QC log), and the office would manually correct the name on the physical slide that was stored in the dermatopathologist's office. 4. There was no procedure providing instructions for how to handle a misidentified specimen. 5. The QC log showed that accession number 24WBDL319 had the "wrong person" identified. 6. Records showed that the report was updated with the correct patient identity, but the physical slide still contained the incorrect patient identity. 7. During the exit interview on 01/16/2025 at 12:25 PM, the OM confirmed that there was no procedure detailing instructions for how to handle a misidentified specimen and that the slide for specimen 24WBDL319 still contained the incorrect patient identity.

D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of the procedure and testing records and interview with the office manager (OM), the laboratory failed to ensure that the procedure matched laboratory practice for histopathology testing. Findings: 1. The office performed patient biopsies and sent the tissue to an outside laboratory for slide processing. The outside laboratory would send the slides and a final report template back to the office where the dermatopathologist would evaluate the slide and record the diagnosis on the final report template. 2. The procedure titled "Histology Quality Control" was reviewed. 3. The procedure referred to how to document specimen rejection if samples were received in incorrect fixative and how to document malfunctions of the tissue processor and other equipment, but the laboratory did not perform any of the tissue and slide processing. 4. The procedure identified quality assurance (QA) logs titled "Specimen Accessioning - Monitoring Form," "Specimen Processing/Staining - Monitoring Form," and "Specimen Reporting - Monitoring Form," none of which were in use. 5. The procedure stated that "The specimen accessioning, processing and reporting monitors are reported on the 'Quality Control Report' forms and presented at the monthly meeting of the Quality Assurance Committee, who evaluates, recommends corrective measures/action and follow-up." The "Quality Control Report" forms were not in use and there was no Quality Assurance Committee that met monthly for QA review. 6. The procedure did not include instructions detailing the steps that should be taken when a misidentified patient was found (cross-refer to tag D5203). 7. During the exit interview on 01/16/2025 at 12:25 PM, the OM confirmed that the "Histology Quality Control" procedure did not match laboratory practice.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(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 and interview with the office manager (OM), the laboratory failed to ensure that the reagents for potassium hydroxide (KOH) preparations were not used beyond their expiration date. Findings: 1. It was observed during a laboratory tour that the KOH reagent lot number K08BP4 expired on November 2011. 2. The KOH patient log did not record which lot number of KOH reagent was in use. 3. During the exit interview on 01/16/2025 at 12:25 PM, the OM confirmed that KOH reagent lot number K08BP4 that expired in November 2011 appeared to be the lot number currently in use for patient testing.