Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D2232549	08/23/2023
Name of Provider or Supplier	**Street Address, City, State**	
Central Dermatology Center	1212 Cedarhurst Drive, Suite 102, Raleigh, NC	

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
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method. This STANDARD is not met as evidenced by: Based on review of validation records and interview with the laboratory director 8/23/23, the laboratory director failed to ensure validation procedures were adequate to determine the performance specifications of the CK 5/6, P63, and CK 5/6 with P63 antibodies used in IHC (immunohistochemical) staining. Findings: Review of validation records for CK 5/6, P63, and CK 5/6 with P63 revealed no documentation of results, no documentation of quality control reactions, and no raw data. The records did not indicate whether the performance of the IHC stains was acceptable. Review of validation records revealed the laboratory director approved the addition of CK 5/6, P63, and CK 5/6 with P63 on 8/4/21. During the exit interview at approximately 1:45 p.m., the laboratory director stated someone from outside the laboratory performed the validation and he did not realize it was incomplete.
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

	This STANDARD is not met as evidenced by: Based on review of personnel records and interview with the histotechnician 8/23/23, the TS (technical supervisor) failed to evaluate the competency for 4 of 4 providers /testing personnel (TP #1, TP #2, TP #3, TP #4) who perform KOH (potassium hydroxide) preps during 2021, 2022, and 2023. Review of personnel records for TP #1, TP #2, TP #3, and TP #4 revealed there were no 2021, 2022, or 2023 competency evaluations available for review. During interview at approximately 11:45 a.m., the histotechnician confirmed that the TS did not perform competency evaluations for TP #1, TP #2, TP #3, and TP #4 during 2021 and 2022. He also verified that the TS did not perform competency evaluations for TP #1, TP #2, TP#3, and TP #4 between 1/1 /23 and 8/23/23.