Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D2312154	(X3) Date Survey Completed 06/24/2025
Name of Provider or Supplier The Derm Collective North Shore, Pllc	**Street Address, City, State** 40 Skokie Blvd, Northbrook, IL	
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
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 laboratory CMS-116 form, policy and procedure, patient testing documentation, and interview with and laboratory representative, the laboratory failed to check SRY-Box transcription factor 10 (Sox 10) Immunohistochemistry (IHC) stain for positive and negative reactivity each time of use for three of three patients reviewed. Findings include: 1. Review of laboratory Clinical Laboratory Improvement Amendments (CLIA) Application for certification (CMS-116) revealed the laboratory was performing SOX 10 IHC staining. 2. The Laboratory procedure titled "Frequency and Record of Quality Control Analyses" states "H & E and standing order stain slide quality control is assessed and documented daily. All Immunohistochemistry and special stain slide quality control is assessed and documented on a case by case basis. Any slide that does not pass the quality assessment by the pathologist will be repeated until the quality of the staining is deemed acceptable. All slide QC documentation is filed and maintained by the referral CLIA-certified laboratory, Consolidated Pathology Consultants" 3. Review of patient testing records found for three of three patients the laboratory failed to review positive and negative reactivity each time of use of SOX 10 IHC stain. A. Case number: CPC25-018786 Date: 03-21-2025 B. Case number: CPC25-015003 Date: 03-06-2025 C. Case number: CPC25-011957 Date: 02-21-2025 4. Interview with Laboratory representative at 12:50 PM on 06-24-2025 confirmed the laboratory failed to document positive and negative reactivity for SOX-10 IHC staining for the three patients reviewed.