

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D2114254	(X3) Date Survey Completed 02/15/2024
Name of Provider or Supplier Lake Shore Dermatology	Street Address, City, State 270 East Center Dr, Ste 130, Vernon Hills, 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	<p>HISTOPATHOLOGY CFR(s): 493.1273(a)(f)</p> <p>(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. (f) The laboratory must document all control procedures performed, as specified in this section.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory records, lack of documentation, and interview with the project manager (PM); the laboratory failed to document the quality control (QC) reactions for immunohistochemical (IHC) staining for eight of eight patient test results in 2022 and 2023. Findings include: 1. Review of the "Lake Shore Dermatology Frequency and Record of Quality Control Analyses" policy revealed; "H & E and standing order stain 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. 2. Review of the "Lake Shore Dermatology Post-analytical Quality Control Procedures" policy revealed; "Microscopic. A detailed description of the microscopic features may be recorded as part of the report. The results of control tissue for the special stains should be recorded when appropriate." 3. Review of patient test results and laboratory QC records, found no documentation of the IHC QC stain results for the following eight of eight IHC patient test results: Report Date Patient ID IHC Stain 10/17/2022 53835</p>

SOX-10 Melan-A PRAME 05/15/2023 50343 SOX-10 PRAME 11/10/2023 10206
SOX-10 Melan-A PRAME 4. On 02/15/2023, at 1:30 p.m., the PM confirmed the
above findings.