Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D2190275	11/22/2021
Name of Provider or Supplier	**Street Address, City, State**	
Dolehide Dermatology	4400 W 95th Street Suite 406, Oak Lawn, 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
D5471	CONTROL PROCEDURES CFR(s): 493.1256(e)(1)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and interview, the laboratory failed to document each lot number of commercially prepared reagents and stains, when opened, to perform Histology staining procedures. Findings include: 1. The laboratory procedures manual, electronic medical records (EMR) patients test logs, and quality control (QC) and maintenance logs from 09/01/21 through 11/22/21 were reviewed. 2. The QC records and patients' test logs revealed the following: *Two (2) Mohs procedures dates were selected for patients, QC, and maintenance logs review: 10/01 /21 and 11/03/21. *The QC logs failed to include the lot numbers and expiration dates of the reagents and stains used for tissue processing for the above dates. 3. The laboratory failed to ensure the lot numbers and expiration dates of reagents and stains used to perform tissue processing and staining are documented and retained for at least two years. 4. On an Initial survey conducted on 11/22/21 at 11:55 AM, the testing personnel confirmed the above findings.
D5821	TEST REPORT CFR(s): 493.1291(k) When errors in the reported patient test results are detected, the laboratory must do the

	following: (k)(1) Promptly notify the authorized person ordering the test and, if applicable, the individual using the test results of reporting errors. (k)(2) Issue corrected reports promptly to the authorized person ordering the test and, if applicable, the individual using the test results. (k)(3) Maintain duplicates of the original report, as well as the corrected report. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to maintain duplicates of the original report, as well as the corrected report when errors in the reported patient test results are detected, affecting one out of one patient. Findings include: 1. The patients' electronic medical record (EMR) test reports, selected patients final reports, and procedures manual were reviewed. 2. Review of three selected patients final pathology reports revealed one patient had two final reports. The laboratory failed to indicate on the changed report that there was a correction. 3. The patient's EMR chart failed to indicate that changes were made to the first pathology report. 4. The laboratory failed to include a step-by-step procedure to identify corrections on patients final reports and in their respective EMR charts. 5. On an Initial survey conducted on 11/22/21 at 11:55 AM, the testing personnel confirmed the above findings.