Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D0391437	04/24/2023
Name of Provider or Supplier	**Street Address, City, State**	
Layton Avenue Dermatology	2923 W Layton Ave, Greenfield, WI	

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
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 surveyor observation of reagents in the laboratory and interview with testing personnel, testing personnel used expired Gill 3 hematoxylin stain four of the last four months. Findings include: 1. Observation of stains in the laboratory on April 24, 2023 at 1:25 PM revealed an opened bottle of Gill 3 hematoxylin, lot 122924, expiration date December 31, 2022. Continued observation showed no other opened hematoxylin stain in the laboratory. 2. Interview with testing personnel (staff A) on April 24, 2023 at 1:25 PM confirmed testing personnel stained all patient Hematoxylin & Eosin slides made after December 31, 2022 using the expired hematoxylin reagent.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory records and interview with testing personnel, the laboratory did not document the testing of the hematoxylin and eosin (H&E) stain

	for intended reactivity for four of four Mohs cases reviewed. Findings include: 1. Random review of records for four Mohs cases performed in 2022 showed no record of stain quality documentation for each day of testing. 2. Interview with testing personnel (staff A) on April 24, 2023 at 1:30 PM confirmed testing personnel had not evaluated and documented the H&E evaluation for intended reactivity each day of use.