Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D1015730	07/25/2023
Name of Provider or Supplier	**Street Address, City, State**	
Livonia Dermatology	14801 Farmington Road, Livonia, MI	

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
D5028	HISTOPATHOLOGY CFR(s): 493.1219 If the laboratory provides services in the subspecialty of Histopathology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493. 1273, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: . Based on record review and interviews, the laboratory failed to verify the accuracy of its Periodic Acid-Schiff special stain testing at least twice annually (refer to D5217), failed to establish a written procedure for its Periodic Acid-Schiff special stain testing (refer to D5401), and failed to perform and document control procedures for its Periodic Acid-Schiff special stains at least each day of use (refer to D5473).
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: . Based on record review and interview with Testing Personnel #2, the laboratory failed to follow its competency assessment policies for 1 (Testing Personnel #2) of 2 testing personnel listed on Form CMS-209. Findings include: 1. A review of the laboratory's personnel records revealed Testing Personnel #2, performing tissue specimen gross examinations, last had their competency assessed on 3/2/22. 2. A review of the laboratory's "Technical Supervisor" policies revealed a section stating, "The technical supervisor is responsible for the technical and scientific oversight of

	the laboratory. The responsibilities are as follows: Evaluate and document performance of individuals responsible for highly complex testing at least semi-annually during the first year they test patient specimens, and then at least annually unless the test methodology and/or instrumentation change." 3. An interview on 7/25 /23 at 12:01 pm with Testing Personnel #2 confirmed their competency assessment had not been completed at least annually according to laboratory policy.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: . Based on record review and interview with Testing Personnel #2, the laboratory failed to verify the accuracy of its Periodic Acid-Schiff special stain testing at least twice annually for 2 (July 2021 to July 2023) of 2 years reviewed. Findings include: 1. A review of the laboratory's "Patient Test Management" policy with a section titled "Testing and Verification" stating, "Four slides (2 cancers, 1 noncancer, 1 PAS) will be sent biannually to an outside laboratory for interpretation." 2. The surveyor requested documentation of the verification of accuracy for its Periodic Acid-Schiff (PAS) special stain testing from July 2021 to July 2023 on 7/25/23 at 11:25 am and it was not made available. 3. An interview on 7/25/23 at 12:01 pm with Testing Personnel #2 confirmed the laboratory had not verified the accuracy of its PAS special stain testing at least twice annually.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: . Based on record review and interview with Testing Personnel #2, the laboratory failed to establish a written procedure for its Periodic Acid-Schiff special stain testing for 2 (July 2021 to July 2023) of 2 years. Findings include: 1. The surveyor observed Schiff's reagent in the laboratory refrigerator during a tour of the laboratory on 7/25 /23 at 9:20 am. 2. A review of the laboratory's procedure manuals revealed a lack of procedure for the performance of Periodic Acid-Schiff special stain testing. 3. An interview on 7/25/23 at 11:43 am with Testing Personnel #2 confirmed the laboratory had not established a test procedure for its Periodic Acid-Schiff special stain testing. 4. An interview on 7/25/23 at 12:01 pm with Testing Personnel #2 revealed the laboratory had performed PAS special stain testing on 9 patients from January to July 2023.
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 record review and interviews, the laboratory failed to perform and document control procedures for its Periodic Acid-Schiff special stains at least each day of use for 9 of 9 patients tested between January to July 2023. Findings include: 1. An interview on 7/25/23 at 11:25 am with Testing Personnel #2 revealed the laboratory performed Periodic Acid-Schiff (PAS) special staining. 2. An interview on 7/25/23 at 11:40 am with the Laboratory Director revealed positive and negative controls for PAS special staining had not been recorded each day of use. 3. An interview on 7/25/23 at 12:01 pm with Testing Personnel #2 revealed the laboratory had performed PAS special stain testing on 9 patients from January to July 2023 and no positive and negative controls had been documented.
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 with Testing Personnel #2, the laboratory failed to issue corrected reports for 3 (Patients DP22-738, MH22-308, and MH23-134) of 13 patient test reports reviewed. Findings include: 1. A review of patient test records revealed the following patients had errors on their test reports without a corrected report issued: a. Patient DP22-738, testing performed on 4/4/22, indicated the site of "Right Tibial" on the test report with a line drawn through it and "perinasal" handwritten next to it. b. Patient MH22-308, testing performed on 09/20/22, indicated the site of "Left Calf" on the test report with a line drawn through it and "Pretibial" handwritten next to it. c. Patient MH23-134, testing performed on 5/25/23, indicated the site of "Left Clavicle" on the test report with a line drawn through it and "Right Cheek" handwritten next to it. 2. An interview on 7/25/23 at 12:01 pm with Testing Personnel #2 revealed the sites that were changed were corrected and a corrected report had not been issued.