Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D0953747	02/24/2022
Name of Provider or Supplier	**Street Address, City, State**	
St Luke's Dermatology	920 E First St Ste 201, Duluth, MN	

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
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 document review and interview with laboratory personnel, the laboratory failed to perform and document activities used to verify the accuracy of 2 of 3 microscopic examinations at least twice annually in 2020 and 3 of 3 microscopic examinations at least twice annually in 2021. Findings are as follows: 1. The laboratory performed microscopic examinations for fungus, parasites, and viruses under the specialty of Microbiology as confirmed by the Clinic Manager (CM) during a tour of the laboratory at 10:00 a.m. on 02/24/22. 2. Requirements for twice annual verification of accuracy testing were established in the laboratory's procedures for performing KOH fungal and yeast preparations (KOH), wet preparations of the skin (WP), and Tzanck preparations (T). 3. Verification of accuracy records for 2020 and 2021 reviewed on date of survey did not include the required number of verifications for each test . See below. 2020 Test Number of verifications WP 0 T 1 2021 Test Number of verifications KOH 1 WP 1 T 1 The laboratory was unable to provide additional verification documentation upon request. 4. The laboratory's patient log indicated patient samples received microscopic examinations for fungus, parasites, and viruses in 2020 and 2021. See below 2020 Test Number of patients WP 4 T 1 2021 Test Number of patients KOH 35 WP 4 T 1 5. In an interview at 12:35 p.m. on 02/24/22, the CM confirmed the above finding. .
D5609	HISTOPATHOLOGY CFR(s): 493.1273(e)(f) (e) The laboratory must use acceptable terminology of a recognized system of disease

	nomenclature in reporting results. (f) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory staff, the laboratory failed to retain lot number and expiration date records for 2 of 2 stains used for Histopathology testing. Findings include: 1. The laboratory performed Mohs micrographic surgery with microscopic examination under the specialty of Histopathology as confirmed by the Clinic Manager during a tour of the laboratory at 10:00 a.m. on 02/24/22. 2. Laboratory policies and procedures did not include instruction to record and retain Hematoxylin and Eosin (H&E) stain lot numbers and expiration dates. 3. Documentation of H&E stain lot numbers and expiration dates was not found during review of laboratory records from September 2020 through February 2022. 4. The laboratory was unable to provide the required documentation upon request. 5. In an interview at 12:25 p.m. on 02/24/22, the Histotechnician confirmed the above finding. .
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory failed to ensure all test result reports included the address of the laboratory location. Findings are as follows: 1. The laboratory performed Mohs micrographic surgery with microscopic examination under the specialty of Histopathology as confirmed by the Clinic Manager during a tour of the laboratory at 10:00 a.m. on 02/24/22. 2. The address of the laboratory location was not included on test result reports reviewed on date of survey. See below Case number Date of testing M20-377 12/22/20 M21-336 11/15/21 3. The estimated Histopathology annual test volume was 388 as indicated on the Clinical Laboratory Improvement Amendments (CLIA) Application for Certification Form CMS-116 obtained during the survey. 4. In an interview at 12:15 p. m. on 02/24/22, the CM confirmed the above finding.