

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D0953747	(X3) Date Survey Completed 03/05/2026
Name of Provider or Supplier St Luke's Dermatology	Street Address, City, State 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
D0000	The Aspirus St Luke's Dermatology laboratory was found to be out of compliance with the regulations of the Clinical Laboratory Improvement Amendments of 1988 (42 C.F.R. part 493) upon completion of the recertification survey performed on March 05, 2026. The following standard-level deficiency was cited: 493.1236 Evaluation of proficiency testing performance 493.1407 Laboratory director responsibilities .
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>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.</p> <p>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 1 of 3 Provider Performed Microscopy (PPM) examinations at least twice annually in 2025. Findings are as follows: 1. The laboratory performed PPM 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 1:05 p.m. on 03/05/26. 2. Requirements for twice annual verification of accuracy testing for parasites were established in the Procedure for Preparing and Interpreting Wet Preparations of the Skin found in the Log & Procedure Manual for Scrapings - KOH, Wet Prep, Tzanck. 3. A single parasite accuracy verification document from 2025 was found during review of laboratory records on date of survey. The laboratory was unable to provide documentation of an additional parasite verification upon request. 4. The laboratory's patient testing log indicated two patient samples received microscopic examinations for parasites in 2025. 5. In an interview at 3:15 p.m. on 03/05/26, the CM confirmed the above finding. *This deficiency was previously cited during the 04/07/16 and 02/24/22 surveys* .</p>

D6004

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(a)(b)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reappoints performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:

. Based on review of laboratory policies and procedures, quality control logs, and previous survey data, the Laboratory Director failed to ensure previously cited deficiencies were corrected in 2025. Findings are as follows: The following deficiency was cited during the 04/07/16 and 02/24/22 surveys and was also out of compliance on 03/05/26. D5217 - the laboratory failed to perform and document activities used to verify the accuracy of Provider Performed Microscopy examinations at least twice annually in 2025