

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D0400519	(X3) Date Survey Completed 11/29/2023
Name of Provider or Supplier South Lake Pediatrics - Minnetonka	Street Address, City, State 17705 Hutchins Drive, Suite 100, Minnetonka, 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
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: . Based on observation and interview with laboratory personnel, the laboratory failed to follow the established Pinworm Procedure in 2022 and 2023. Findings are as follows: 1. The laboratory performed pinworm preparations testing under the sub-specialty of Parasitology as confirmed the Technical Consultant (TC) during a tour of the laboratory at 1:00 p.m. on November 29, 2023. 2. The Nikon Alphaphot YS2 microscope used to perform manual pinworm preparations was observed as present and available during the tour of the laboratory. 3. The Pinworm Procedure, dated 6/17 /99, signed by the current Laboratory Director 06/24/14, was found in the 3-Ring Laboratory Procedure Manual. The procedure directed the staff to have the physician view the specimen and verify results, the reviewing physician should then initial the daily log and the lab slip. 4. Review testing documentation for a patient who had a pinworm procedure performed on October 12, 2023, found no evidence the physician had reviewed, verified, and initialed the results. 4. In an interview at 3:30 p.m. on November 29 2023, the TC confirmed the written procedure was out of date with the current practice and the laboratory no longer follows the written procedure. .</p>