Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D0695974	02/28/2024
Name of Provider or Supplier	**Street Address, City, State**	
Shoreview Pediatrics Sc	2524 E Webster Place #301, Milwaukee, 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
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on surveyor review of procedures, observation of laboratory supplies, and interview with Testing Personnel (Staff A), one of one 'Urine Culture with Urine Culturia' procedure was not specific for the product in use in the laboratory and did not include instructions for inoculation of the culture media. Findings include: 1. Review of the 'Urine Culture with Urine Culturia' procedure showed the procedure identified the culture media used as Urine EMB (Eosin Methylene Blue) agar from Life Sign in Somerset, New Jersey. Further review showed no instructions for inoculating or labeling the culture media other than directing testing personnel to

	inoculate the media immediately following collection. 2. Observation of urine culture media in the laboratory on February 28, 2024, at 11:40 AM revealed Uricult CLED (Cystine Lactose Electrolyte Deficient)/EMB Urine Culture Paddles were available for culturing urine samples. Interview with Staff A during the observation confirmed the laboratory used the Uricult Paddles for culturing urine samples. 3. Further interview with Staff A on February 28, 2024, at 11:50 AM confirmed the procedure did not provide step-by-step instructions for performance of the urine culture procedure.
D6072	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(3) Each individual performing moderate complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory procedures and records and interview with Testing Personnel (Staff A), testing personnel did not document monthly quality control testing as required by the laboratory's IQCP (Individualized Quality Control Plan) in three of fourteen months from January 2023 through February 2024 for testing with the Alethia Pertussis DNA amplification assay. Findings include: 1. Review of the laboratory's IQCP procedures for the Alethia Pertussis DNA amplification assay showed positive and negative external quality control sample testing was required monthly. 2. Review of Pertussis 'Control Log Sheet for Illumigene' forms from January 2023 through February 2024 revealed no records of external quality control testing from December 2023 or January and February 2024. Review of patient test records showed testing personnel performed pertussis testing on samples from two patients on January 6, one patient on January 18 (two tests performed, first result was invalid), and one patient on February 15, 2024. 3. Interview with Staff A on February 28, 2024, at 11:50 AM confirmed testing personnel did not document monthly external control testing for the Alethia Pertussis DNA amplification assay in December 2023 or January and February 2024.