Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D0695974	05/13/2026
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
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 surveyor review of procedures and laboratory records and interview with the laboratory director, the director (Staff A) did not follow laboratory procedures and did not delegate in writing the technical consultant responsibilities performed by one of one staff member (Staff B) assigned the responsibilities. Findings include: 1. The 'Policy' section, point 9. of the "Testing Personnel Competency Policy and Procedure" stated, "Unit managers, who fill the CLIA role of technical supervisor, are required to have a competency assessment on the federal regulatory responsibilities and additional responsibilities that have been delegated to them from the laboratory director. These delegated responsibilities must be in writing." 2. Review of laboratory 'Competency Assessment Forms' showed Staff B performed competency assessments of testing personnel, a technical consultant responsibility. 3. Review of quality assurance and competency assessment records showed no evidence of delegation of technical consultant responsibilities to Staff B or evaluation of Staff B in performing those responsibilities. 4. Interview with the laboratory director on May 13, 2026, at 12: 15 PM confirmed they had not delegated the technical consultant responsibilities performed by Staff B in writing and had not documented competence of Staff B in performing the responsibilities.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established

	and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur; This STANDARD is not met as evidenced by: Based on surveyor review of an individualized quality control plan (IQCP) and review and comparison of patient test and quality control (QC) records and interview with the laboratory director (Staff A), the director did not ensure the quality control program for the Meridian illumigene Bordetella pertussis test was maintained in four of twelve months reviewed. Findings include: 1. Review of the policy, "illumigene Pertussis Quality Control Plan & Procedure Plan", approved by the laboratory director on November 17, 2020, showed in the 'QC Testing Frequency and Documentation' section, "A positive and negative test are performed every 30 days and/or when a new lot is opened". 2. Review of patient Pertussis test records documented on 'Specimen Sheet for illumigene' from January through December 2025, showed personnel documented the following lot numbers used for patient testing: Lot Number | through date 480750T016 | January 1 - 15 480750U020 | January 15 480750U017 | January 24 -July 12 480750U020 | September 12 - December 31 3. Review of Pertussis QC records showed personnel performed QC testing with the following lot numbers from January through December 2025: Lot Number | Months tested 480750U017 | January 23, February and March 479930T010 | April 21, May and June 480750U020 | July 22 479930T010 | August 20 480750U020 | October 9, November and December 4. Comparison of patient test records and QC test records showed the lot number of Pertussis tests personnel used for patient testing from January 24 through July 12, 2025, was not tested with QC material in April, May, June or July. 5. Interview with Staff A on May 13, 2026, at 12:15 PM confirmed the laboratory director did not maintain the QC program to ensure personnel tested the lot number of tests used for patient testing with quality control material each 30 days.