Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D0695974	04/26/2022
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
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory records and interview with the nurse manager, staff A, the laboratory director did not review and approve the performance specification verification records on the replacement Revogene Group A Strep analyzer prior to reporting patient results. Findings include: 1. Review of the "Revogene Instrument Validation" form showed the laboratory installed a replacement Revogene analyzer on June 26, 2021 and started reporting patients on July 2, 2021. Further review showed the laboratory director reviewed and accepted the validation on August 26, 2021. 2. Review of the daily "Revogene Specimen Log" reports showed ninety patients were run between July 2, 2021 and August 26, 2021. 3. Interview with staff A on April 26, 2022 at 11:15 AM confirmed the laboratory director did not review and approve the performance specification verification records on the replacement Revogene Group A Strep analyzer prior to reporting patient results. This is a repeat deficiency from March 31, 2008.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations

	Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on surveyor review of the Individualized Quality Control Plan (IQCP), quality control (QC) records and interview with the nurse manager, staff A, the laboratory did not perform two levels of quality control on each day of patient testing and had not developed Quality Control Plan (QCP) for the Revogene Group A Strep analyzer. Findings include: 1. Review of IQCP records for the Revogene Group A Strep analyzer showed a risk assessment performed on the analyzer. Further review showed no evidence of a QCP. 2. Review of QC records for the Revogene Group A Strep analyzer showed QC was performed monthly and with each new lot. 3. Interview with staff A on April 26, 2022 at 11:12 AM confirmed the laboratory did not perform two levels of quality control on each day of patient testing and had not developed an IQCP for the Revogene Group A Strep analyzer.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on surveyor review of the Individualized Quality Control Plan (IQCP) and interview with the nurse manager, staff A, the laboratory did not have a written procedure to monitor, assess, and when indicated, correct problems identified for the ongoing monitoring of the effectiveness of their IQCP for the Revogene Group A Strep analyzer. Findings include: 1. Review of IQCP records for the Revogene Group A Strep analyzer showed a risk assessment performed on the analyzer. Further review showed no evidence of a Quality Assessment (QA) plan. 2. Interview with staff A on April 26, 2022 at 11:12 AM confirmed the laboratory did not have a written procedure to monitor, assess, and when indicated, correct problems identified for the ongoing monitoring of the effectiveness of their IQCP for the Revogene Group A Strep analyzer.