Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D0911694	04/24/2018
Name of Provider or Supplier	**Street Address, City, State**	
Wildwood Family Clinic Sc	251 East Cottage Grove Rd, Cottage Grove, 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
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on surveyor review of proficiency testing (PT) records and interview with the Technical Consultant who is also the Lab Director, the laboratory failed to include all testing personnel who routinely perform non-waived testing in 2016 and 2017. Findings include: 1. Review of PT records for non-waived testing show that one of four Testing Personnel (TP), TP A, has not participated in PT in 2016 and 2017. TP A performed testing in the laboratory in 2016 and 2017. 2. Interview with the Technical Consultant/Lab Director on April 24, 2018 at 11:00 AM confirmed that TP A has not participated in PT in 2016 and 2017.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory quality control records and interview with the laboratory Technical Consultant who is also the Lab Director, the laboratory does not

	use an elevated serum total bilirubin control for monitoring the abnormal range of neonatal bilirubin testing. Findings include: 1. Review of laboratory quality control (QC) records for the total bilirubin assay show that two levels of QC are performed on a daily basis. The QC records for the total bilirubin assay show that an elevated serum based total bilirubin control for monitoring the abnormal range of neonatal bilirubin is not assayed when performing neonatal bilirubin testing. 2. Interview with the Technical Consultant/Lab Director on April 24, 2018 at 12:30 PM confirms that an elevated serum based total bilirubin control is not used to monitor the abnormal range when performing neonatal bilirubin testing.
D6047	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b(8)(i) The procedures for evaluation of the competency of the staff must include, but are not limited to direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. This STANDARD is not met as evidenced by: Based on surveyor review of competency assessment records and interview with the Technical Consultant, the Technical Consultant has not documented the direct observations of routine patient testing for four of four Testing Personnel in 2017. Findings include: 1. Review of competency assessment records show no evidence of direct observation of routine patient testing for four of four Testing Personnel in 2017. 2. Interview with the Technical Consultant on April 24, 2018 at 10:30 AM confirms direct observation of routine patient testing was not documented as part of the competency evaluation procedures.