Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D1018667	02/08/2018
Name of Provider or Supplier	**Street Address, City, State**	
Lakewood Health System - Pillager Clinic	653 Pillsbury St N, Pillager, 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
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory failed to evaluate unacceptable Hematology proficiency testing (PT) results. Findings are as follows: 1. The laboratory performed Hematology testing as confirmed by Technical Consultant 1 (TC1) during a tour of the laboratory on 02/08/18 at 1:40 p.m. 2. The laboratory performed PT using the American Proficiency Institute (API) provider. 3. The laboratory received unacceptable Monocytes/Mids PT results from API for the event listed below. Event ID Lab Result API expected 2017-1 HEM-05 60.8 7.8-11.7 4. An evaluation of the unacceptable PT result was not found during review of laboratory records. The laboratory was unable to provide an evaluation upon request. 5. In an interview on 02/08/18 at 3:50 p.m., TC1 confirmed a documented evaluation of the unacceptable results was not performed.
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 document review and interview with laboratory personnel, the laboratory failed to verify performance specifications for 1 of 1 new tests implemented in 2017. Findings are as follows: 1. The laboratory performed General Immunology testing as confirmed by Technical Consultant 1 (TC1) during a tour of the laboratory on 02/08 /18 at 1:40 p.m. 2. An AmniSure Rupture of Fetal Membranes (ROM) test kit was observed as present and available for use during the tour. 3. The Aminsure [sic] patient testing log indicated AmniSure ROM testing was initiated on 01/24/17. Seven patient specimens were tested between 01/24/17 and date of survey, 02/08/18. 4. Performance verification (PV) documentation for the AmniSure ROM test was not found in laboratory records. The laboratory was unable to provide PV documents upon request. 5. In an interview on 02/08/18 at 4:55 PM, TC1 confirmed a PV had not been performed for the AmniSure ROM test.
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 document review and interview with laboratory personnel, the laboratory failed to perform quality control activities as established in an Individualized Quality Control Plan (IQCP) for General Immunology testing. Findings are as follows: 1. The laboratory performed General Immunology testing as confirmed by Technical Consultant 1 (TC1) during a tour of the laboratory on 02/08/18 at 1:40 p.m. 2. An AmniSure Rupture of Fetal Membranes (ROM) test kit was observed as present and available for use during the tour. 3. Quality control (QC) performance was required with every new lot or shipment as established in the Amnisure IQCP. 4. QC was performed on 12/11/16 at another location as indicated on the Aminsure [sic] patient testing log and information obtained from TC1. 5. The Aminsure [sic] patient testing log indicated 7 patient specimens received AmniSure ROM testing between 01/24/17 and date of survey, 02/08/18. 6. In an interview on 02/08/18 at 5:00 p.m., TC1 confirmed AmniSure ROM QC had not been performed at the Lakewood Health System - Pillager location as required in the IQCP.