Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D0406224	02/07/2019
Name of Provider or Supplier	**Street Address, City, State**	
Lakewood Health System	49725 County 83, Staples, 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
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory failed to verify the accuracy of non-regulated Immunology and Hematology analytes at least twice annually in 2017 and 2018. Findings are as follows: 1. The laboratory performed Immunology and Hematology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory on 02/07/19 at 8:20 a.m. 2. The CRP* test and Semen Analysis microscopic examination were included on the Tests Performed at Lakewood Health System policy provided by the laboratory. 3. Twice annual verification of accuracy documents for CRP and Semen Analysis (motility and grade) were not found during review of laboratory records from 2017 and 2018. The laboratory was unable to provide the documents upon request. 4. In an interview on 02 /07/19 at 4:35 p.m. and 11:40 a.m. respectively, the GS confirmed the accuracy of the CRP test and Semen Analysis (motility and grade) had not been verified twice annually in 2017 and 2018. *C-Reactive Protein
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 observation, document review and interview with laboratory personnel, the laboratory failed to include Chemistry and Hematology reference ranges in the procedure manual. Findings are as follows: 1. The laboratory performed Chemistry and Hematology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory on 02/07/19 at 8:20 a.m. 2. A Centaur immunoassay analyzer and a Stago Compact analyzer were observed as present and available for use during the tour of the laboratory. 3. The reference range for the Estradiol immunoassay test was not found in the Centaur Operation procedure located in the online procedure program LakeNet. 4. The reference range for the International Normalized Ratio (INR) was not found in the STAGO Protime procedure located in the online procedure program LakeNet. 5. The missing reference ranges were not found elsewhere within the online procedure program LakeNet. 6. In an interview on 02/07/19 at 4:18 p.m., the GS confirmed the above findings. .
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 observation, document review and interview with laboratory personnel, the laboratory failed to perform quality control (QC) upon receipt of Microbiology media. Findings are as follows: 1. The laboratory performed Microbiology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory on 02/07/19 at 8:20 a.m. 2. VersaTREK Blood Culture bottles were observed as present and available for use during the tour of the laboratory 3. The manufacturer's Certificate of Analysis and Certificate of Conformance were used in lieu of performing sterility, appearance and ability to support growth QC on new lots or shipments of Versa TREK Blood Culture bottles. Requirements to perform QC upon receipt of VersaTREK Blood Culture bottles were not found in laboratory procedures. 4. The laboratory did not complete an Individualized Quality Control Plan (IQCP) to reduce

	or eliminate the required sterility, appearance and ability to support growth QC. 5. In an interview on 02/07/19 at 2:46 p.m., the GS confirmed an IQCP was not in place to reduce or eliminate required QC for the VersaTREK Blood Culture bottles.
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the technical supervisor failed to ensure testing personnel (TP)received competency assessments for all test procedures performed in 2017 and 2018. Findings are as follows: 1. The laboratory performed Hematology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory on 02/07/19 at 8:20 a.m. 2. Competency assessment documents for 16 of 16 fully trained TP in 2017 and 19 of 19 fully trained TP in 2018 did not include an evaluation of the following items: Analyzer (Test) - Streck ESR-Auto Plus (Erythrocyte Sedimentation Rate) Microscopic Examinations (Tests) -Semen analysis (count, motility, and grade) 3. The laboratory was unable to provide the missing competency documents upon request. 4. In an interview on 02/07 /19 at 11:30 a.m., the GS confirmed evaluations of the above items were not included in the 2017 and 2018 competency assessments.