Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D0674215	04/10/2018
Name of Provider or Supplier	**Street Address, City, State**	
Lakewood Health System-Eagle Valley Clinic	815 Hwy 71 South, Eagle Bend, 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
D2010	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2) The laboratory must test samples the same number of times that it routinely tests patient samples. This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory failed to ensure hematology proficiency testing samples were tested consistent with the number of times the laboratory routinely tested patient samples. Findings are as follows: 1. The laboratory performed Hematology testing as confirmed by Technical Consultant 1 (TC1) during a tour of the laboratory on 04/10/18 at 11:05 a.m. 2. The laboratory performed proficiency testing (PT) for Hematology using the American Proficiency Institute (API) proficiency testing provider. 3. Hematology PT samples HEM-11 through HEM-15 from the API 2016 3rd event were tested on multiple days as indicated on test result documents generated by the hematology analyzer. See below for date and time of day testing was performed. 11/10/16 11/11/16 Sample HEM-11 13:21 13:19 HEM-12 13:22 13:21 HEM-13 13:24 13:22 HEM-14 13:25 13:24 HEM-15 13:27 13:25 4. In an interview on 04/10/18 at 12:05 p.m., TC1 confirmed the PT samples had been tested on multiple days and patient specimens would not routinely be handled in this manner.
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 ensure the reportable range obtained during performance verification of a new Hematology analyzer was accurate in the procedure manual. Findings are as follows: 1. The laboratory performed Hematology testing as confirmed by Technical Consultant 1 (TC1) during a tour of the laboratory on 04/10 /18 at 11:05 a.m. Hematology testing volume was estimated at 2,305 annually. 2. A Sysmex XP 300 hematology analyzer was observed as present and available for use during the tour of the laboratory. The laboratory completed performance verification (PV) activities in January 2018 and began testing patient specimens using this analyzer on 02/07/18 as indicated by TC1 during the tour. 3. The Hemoglobin (HGB) reportable range found in the Sysmex XP-300 procedure found in the online procedure program LakeNet did not reflect the actual reportable range values obtained by the laboratory during the PV. See below. Analyte PV Procedure HGB 0-22.9 0.1-25 4. In an interview on 04/10/18 at 1:00 p.m., TC1 confirmed the above finding and stated the laboratory had adopted the manufacturer's analytical measurement range for HGB as the reportable range in procedure.