Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D0665286	10/09/2019
Name of Provider or Supplier	**Street Address, City, State**	
Avera Granite Falls Medical Center	345 10th Avenue, Granite Falls, 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
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). 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 three 2019 proficiency testing (PT) scores when the PT program did not obtain the agreement required for scoring. Findings are as follows: 1. The laboratory performed Microbiology and Chemistry testing as confirmed by the General Supervisor during a tour of the laboratory at 8:10 a.m. on 10/09/19. 2. The laboratory performed PT using the American Proficiency Institute (API) provider. 3. One Microbiology and two Chemistry results from the first 2019 Hematology PT event were not graded by API due to lack of consensus. See below for sample identifications (ID) and analytes. Sample ID Analyte US-02 Urine Sediment UA-01 Urobilinogen VKP-01 Vaginal Wet Prep 4. The API report referred the laboratory to the expected result data summaries for evaluation of the non-graded test results. The data summaries for the above analytes were not present in laboratory records. Evaluations of the non-graded results were not found in laboratory records. The laboratory was unable to provide evaluations of the non-graded results upon request. 5. In an interview on 10/09/19 at 10:55 a.m., the Technical Supervisor confirmed the above finding.
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 accurate reference intervals (normal values) for two analytes in the procedure manual. Findings are as follows: 1. The laboratory performed Hematology testing as confirmed by the General Supervisor during a tour of the laboratory on 10/09/19 at 8:10 a.m. 2. A Beckman Coulter DXH-600 hematology analyzer and a Hematechnologies ESR Stat Plus automated sedimentation rate analyzer were observed as present and available for use during the tour of the laboratory. 3. The White Blood Cell (WBC) reference intervals found in the Normal Values Hematology Adult table provided by the laboratory was discrepant with that indicated on the patient test report reviewed on date of survey. See below. Analyte Table Patient Report WBC 4.5 - 11.0 4.0 - 11.0 3. The male patient Erythrocyte Sedimentation Rate (ESR) reference intervals in the Erythrocyte Sedimentation Rate (ESR) ESR STAT PLUS procedure, located in the Hematology Procedure Manual, was discrepant with that indicated on the patient test report reviewed on date of survey. See below. Analyte Procedure Patient Report ESR 0-10 0-15 4. In an interview on 10/09/19 at 3:30 p.m. and 3:10 p.m. respectively, the GS confirmed the above finding. *This is a repeat finding. D5403 was previously cited during the 05/03 /18 survey*