

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D0665286	(X3) Date Survey Completed 10/06/2023
Name of Provider or Supplier Avera Granite Falls Medical Center	Street Address, City, State 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
D0000	The Avera Granite Falls Medical Center laboratory was found to be out of compliance with the regulations of the Clinical Laboratory Improvement Amendments of 1988 (42 C.F.R. part 493) upon completion of the recertification survey completed on October 6, 2023. The following standard-level deficiencies were cited: 493.1251 Procedure Manual 493.1256 Control Procedures .
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: . Based on observation and interview with laboratory personnel, the laboratory failed to follow the Hematology Stain established procedures in 2022 and 2023. Findings are as follows: 1. The laboratory performed manual differential blood smear testing under the specialty of Hematology as confirmed the General Supervisor (GS) during a tour of the laboratory at 10:10 a.m. on October 5, 2023. 2. The AZER Scientific Easy III Stains used to perform manual blood smears were observed during the tour of the laboratory. It was noted during the tour that the laboratory was staining the slides straight from the three solutions, not making aliquots from a larger stock bottle. 3. Review of the HEM 225 H 11 Hematology Stain procedure found the staff were directed to transfer each solution into staining dishes and keep covered when not in use. 4. In an interview at 11:30 a.m. on October 6, 2023, the GS confirmed the laboratory staff were not transferring the solution to staining dishes and stated that the policy must be out of date with current practice. .</p>
D5473	CONTROL PROCEDURES

CFR(s): 493.1256(e)(2)(g)

(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (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 document Hematology quality control (QC) procedures performed to test AZER Scientific Easy III stain for intended reactivity each day of use from October 2021 through October 2023. Findings are as follows: 1. The laboratory performed manual differential blood smear testing under the specialty of Hematology as confirmed the General Supervisor (GS) during a tour of the laboratory at 10:10 a.m. on October 5, 2023. 2. The AZER Scientific Easy III Stains and Olympus CX43 microscope used to perform manual blood smears were observed as present and available for use during the tour of the laboratory. 3. The HEM 222 H 9 Manual Differential, Peripheral Smear, and-or Slide Review policy, established under section D, Staining and Characteristics, acceptable staining characteristics to ensure were met prior to the interpretation of a slide and if these were not met the laboratory staff were instructed to make a new slide. Documentation of these staining characteristics was not established in policy. 4. The hematology printout for patient account #: GRXXXXXXXX408 who had a blood smear performed on May 2, 2023, was reviewed on the day of survey, October 6, 2023. Documentation of acceptable stain characteristics, quality control check, could not be found for the day of patient testing. 5. QC documentation for each day of patient testing was requested and could not be provided by the laboratory for the previous 2 years. 6. In an interview at 11:45 a.m. on October 6, 2023, the GS confirmed the above findings.