Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D0405291	04/14/2023
Name of Provider or Supplier	**Street Address, City, State**	
Pipestone County Medical Center Laboratory	916 4th Ave Sw, Pipestone, 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 review proficiency testing (PT) results for four (4) of twenty (20) PT events completed in 2021 and 2022. Findings are as follows: 1. The laboratory performed Microbiology, Diagnostic Immunology, Chemistry, Hematology, and Immunohematology testing as confirmed by Technical Consultant 1 (TC1) during a tour of the laboratory at 12:50 p.m. on April 13, 2023. 2. The laboratory performed PT using the American Proficiency Institute (API) provider. 3. The laboratory failed to review the PT results from API for the following events until April 11, 2023, 2 days prior to the announced on-site CLIA survey: *2021 Hematology/Coagulation 3rd Event *2021 Microbiology 3rd Event *2021 Chemistry-Core 3rd Event 4. There was no evidence of laboratory review for API 2022 Immunology/Immunohematology 1st Event. 5. Investigation and corrective action documentation for the non-graded scores found on the 2021 Hematology/Coagulation 3rd Event and 2021 Microbiology 3rd Event evaluation summaries could not be found in laboratory records. The laboratory was unable to provide investigation and data summary records upon request. 6. In an interview at 2:55 p.m. on April 13, 2023, TC1 confirmed the above finding. .
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) 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. This STANDARD is not met as evidenced by: . Based on document review, observation, and interview with laboratory personnel, the laboratory failed to include a written procedure in the policy database for all tests performed by the laboratory. Findings are as follows: 1. The laboratory performed back-up Chemistry testing on the i-STAT point of care instrument, including the Chem 8, G3+ and Troponin cartridges as confirmed by Technical Consultant 1 (TC1) during a tour of the laboratory at 12:50 p.m. on April 13, 2023. 2. An i-STAT point of care instrument was observed as present and available for use during a tour the tour of the laboratory. 3. Written procedures for the testing performed on the i-STAT were not found in the electronic policy database, PolicyStat. 4. The laboratory was unable to provide these procedures upon request. The laboratory was able to provide a one page overview of testing performed on the i-STAT that was posted in the laboratory at request on April 13, 2023. The laboratory was also able to provide the manufacturers operators manual on April 14, 2023. The Laboratory Director had not signed either of the provided documents nor did they contain all the required elements of a test procedure. 5. In an interview at 8:30 a.m. on April 14, 2023, TC1 confirmed the above findings. .
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 observation, document review, and interview with laboratory personnel, the laboratory failed to demonstrate that it could obtain a comparable reportable range to the one established by ALCOR for the miniiSED ESR test system and verify the appropriate reference intervals for the laboratory's patient population prior to reporting patient test results in July 2021. Findings are as follows: 1. The laboratory performed Erythrocyte Sedimentation Rate (ESR) testing under the specialty of Hematology as confirmed by Technical Consultant 1 (TC1) during a tour of the laboratory at 12:50 p.m. on April 13, 2023. 2. The ALCOR Scientific miniiSED ESR analyzer was observed as present and available for use during the tour of the laboratory. 3. Review of the performance verification documents provided for the ALCOR miniiSED, completed by the laboratory in July 2021, found the laboratory had not verified the normal ranges (reference intervals) for the laboratory's patient population nor had the laboratory demonstrated that they could obtain a reportable range comparable to the manufacturer. 4. The laboratory was unable to provide the missing verification records when requested on April 14, 2023. 5. In an interview at 10:50 a.m. on April 14, 2023, TC1 confirmed the laboratory had not performed the normal range or reference range elements of a performance verification prior to testing patient specimens in July 2021. .

D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the laboratory failed to ensure reference intervals were consistent between a Chemistry and Hematology procedures and a patient test reports. Findings are as follows: 1. The laboratory performed Thyroid-stimulating hormone (TSH) which falls under the specialty of Chemistry testing and Hemoglobin (HGB) which falls under the specialty of Hematology testing as confirmed by the Technical Consultant 1 (TC1) during a tour of the laboratory at 12:50 p.m. on April 13, 2023. 2. A Beckman Coulter Access 2, which TSH testing is performed on, and the Sysmex XN550 and XN359, which HGB testing is performed on, were observed as present and available for use during the tour of the laboratory. 3. The TSH reference intervals listed in the Thyroid Stimulating Hormone (TSH) - Access 2 procedure located in PolicyStat electronic policy database, was not consistent with that included on the test report for patient XXX479, tested on 07/01/22, reviewed on date of survey, 4/13/23. See below Analyte Procedure Report TSH 0.35-4.94 mIU/mL 0.45-5.33 mIU/mL 4. The HGB reference intervals listed in the PCMC Avera Health Hematology Reference Ranges, located in PolicyStat electronic policy database, was not consistent with that included on the test report for patient XXX065, tested on 01/23/23, reviewed on date of survey, 4/14/23. See below Analyte Procedure Report HGB 14.0-18.0 g/dL 14.0-17.5 g/dL 5. In an interview at 10:15 a.m. on April 14, 2023, TC1 confirmed the above findings. .
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the Technical Supervisor failed to assess the competency at least annually for one of nine tenured testing personnel in 2022. Findings are as follows: 1. The laboratory performed Microbiology, Diagnostic Immunology, Chemistry, Hematology, and Immunohematology testing as confirmed by Technical Consultant 1 (TC1) during a tour of the laboratory at 12:50 p.m. on April 13, 2023. 2. The following non-waived test systems, analyzers, devices, and test kits were observed as present and available for use during the tour: Siemens Dimension EXL chemistry analyzer Beckman Coulter Access 2 immunoassay analyzer Radiometer ABL80 blood gas test analyzer Abbott i-STAT device Sysmex XN-550 and Sysmex XN-350 hematology analyzers Stago Compact Max coagulation analyzer ALCOR MiniiSED device MTS Immunohematology test system Cepheid GeneExpert PCR system Medtox Urine Drug Screen test system Vitek2 ID and Sensitivity BactT Alert 3D60 Blood Culture

	system Microscopes and stains for microscopic examinations Fungal exam Vaginal preparation Gram Stain Manual differential Body fluid cell counts SureVue Serum hCG test kit 3. Annual competency assessment documentation for the above tests was not found during review of 2022 laboratory records for Testing Personnel 8. 4. The laboratory was unable to provide the missing records upon request. 5. In an interview at 2:22 p.m. on April 13, 2023, the TC1 confirmed the above finding. .