

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D0405291	(X3) Date Survey Completed 05/27/2021
Name of Provider or Supplier Pipestone County Medical Center Laboratory	Street Address, City, State 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
D5421	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: . Based on observation, record review, and interview with laboratory personnel, the laboratory failed to complete performance verification activities for 1 of 3 new tests implemented by the laboratory between March 2019 and May 2021. Findings are as follows: 1. The laboratory performed Chemistry testing as confirmed by the General Supervisor (GS) during a tour of the laboratory at 8:20 a.m. on 05/27/21. 2. An Abbott i-STAT analyzer was observed as present and available for use during the tour of the laboratory. The i-STAT CHEM8+ cartridge was used as a backup method when the primary Chemistry analyzer was unavailable for use as indicated by the GS during the tour. 3. The laboratory implemented use of the non-waived CHEM8+ cartridge on 03/11/20 as indicated in laboratory records. Documentation of performance verification (PV) activities for the non-waived CHEM8+ cartridge was not found in laboratory records. The laboratory was unable to provide PV documentation upon request. 4. The laboratory's Abbott i-STAT Patient Result Log indicated 35 patient samples were tested using the i-STAT CHEM8+ cartridges between 03/11/20 and 05/27/21. See below. Month Number tested 2020 March 0 April 0 May 1 June 9 July 0 August 1 September 5 October 1 November 6 December 1 2021 January 3 February 1 March 6 April 0 May 1 5. In an interview at 4:15 p.m. on 05/27/21, the GS confirmed the above finding.</p>