Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D2162472	01/12/2021
Name of Provider or Supplier	**Street Address, City, State**	
Saginaw Valley Medical Center	3170 Hallmark Court, Saginaw, MI	

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
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: . Based on record review and interview with Technical Consultant (TC) #2, the laboratory failed to verify the toxicology performance specifications for 2 (Buprenorphine [BUP] and Tetrahydrocannabinol [THC]) of 10 tests performed during the 11 (February 2020 to January 2021) months of operation. Findings include: 1. A record review revealed the laboratory failed to verify the performance specifications for 2 (BUP and THC) of 10 toxicology tests. Refer to D5421. 2. An interview on 1/12/2021 at approximately 10:09 am with TC2 confirmed the performance specification were not available on the day of the survey.
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 record review and interview with Technical Consultant (TC) #2, the laboratory failed to verify the performance specifications for 2 (Buprenorphine [BUP] and Tetrahydrocannabinol [THC]) of 10 toxicology tests during the 11 (February 2020 to January 2021) months of operation. Findings include: 1. A review of the laboratory's patient test reports revealed the laboratory was performing and reporting out 2 (BUP and THC) of 10 toxicology tests with no documentation of performance verification during the 11 months of operation. 2. A review of the laboratory's "Performance Validation Summary" revealed a lack of documentation of verification of performance specifications for BUP and THC testing during the initial performance verification studies. 3. When requested on 1/12/2021 at approximately 10:09 am by the surveyor, the verification of performance specification data for BUP and THC testing was not available. 4. An interview on 1/12/2021 at approximately 10:09 am with TC2 confirmed the verification of performance specification data was not made available to the surveyor.
D5803	TEST REPORT CFR(s): 493.1291(b) Test report information maintained as part of the patient's chart or medical record must be readily available to the laboratory and to CMS or a CMS agent upon request. This STANDARD is not met as evidenced by: . Based on document review and interview with Technical Consultant (TC) #2, the laboratory failed to have the final toxicology report maintained as part of the patient's chart or medical record for 1 (#1) of 9 patient charts audited. Findings include: 1. A record review revealed lack of documentation of the final toxicology report for 1 (#1) of 9 patient charts audited in the patient's electronic medical record (EMR) system. 2. On 1/12/2021 at 11:03 am when queried, TC2 was not able to provide the surveyor the final report requested. 3. A interview on 1/12/2021 at 11:03 am, TC2 confirmed the final toxicology report was not part of the patient's EMR report.