Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	18D0327089	05/30/2019
Name of Provider or Supplier	**Street Address, City, State**	
Medical Center At Caverna, The	1501 South Dixie Hwy, Horse Cave, KY	

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	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 staff interview on 05/29/2019 and 05/30/2019, the laboratory failed to verify the performance specifications established by the manufacturer for accuracy and precision when the Sed Rate Mini-Cube was installed 02/01/2019. Findings include: 1. Review of records of installation performed 02/01/2019, failed to reveal verification of accuracy to ensure the testing method produced correct results. 2. Review of records of installation performed 02/01/2019, failed to reveal assessments of day-to-day, run-to-run, and with-in run precision to ensure reproducibility was verified prior to reporting patient results. The Technical Supervisor acknowledged in an interview at 10:00 AM on 05/30/2019, the laboratory failed to have a system in place to demonstrate the laboratory can obtain performance specifications comparable to those established by the manufacturer for accuracy and precision prior to patient testing.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at

	least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on record review and staff interview on 05/29/2019 and 05/30/2019, the laboratory failed to perform and document weekly maintenance on the MTS Dispenser since 07/21/2017, as required by the manufacturer of the MTS Gel Test System. Findings include: Review of the policy for the MTS Gel Test System revealed under Weekly Maintenance "Clean the MTS Dispenser with 70% isopropyl alcohol and rinse with deionized or distilled water. Record the cleaning in the Equipment Quality Control Log." Review of the Equipment Quality Control Log failed to reveal documentation of weekly maintenance of the MTS Dispenser since 07 /21/2017. The Technical Supervisor acknowledged in an interview at 2:00 PM on 05 /29/2019, the laboratory failed to establish a system to ensure maintenance procedures were performed and documented as required by the manufacturer.