Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	26D0446044	12/15/2020
Name of Provider or Supplier	**Street Address, City, State**	
Jefferson City Medical Group	1241 W Stadium Blvd, Jefferson City, MO	

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 review of the procedure manuals, lack of performance verification records and interview with the technical supervisors (TS) #1 and TS #2 confirmed the laboratory failed to meet the requirements specified in 493.1250. (Refer to D5407, D5421)
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on the review of the procedure manual for the Roche Cobas 8000 and interview with the Technical Supervisor (TS) #1, confirmed the laboratory director (LD) failed to approve the procedure manual. Findings: 1. Review of the procedure manual in use by the laboratory for the Roche Cobas 8000 confirmed the LD failed to approve the procedure manual. 2. Interview with the TS #1 on December 15, 2020 at 10:00 AM confirmed the LD failed to approve the procedure manual.

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 review of the performance verification procedures for the Roche Cobas 8000 chemistry analyzer, Sysmex CA-600 coagulation analyzer, Cepheid GeneXpert CT/NG analyzer and the interview with the technical supervisors (TS) #1 and # 2, the laboratory failed to verify the manufacturer's reference intervals with the laboratory's normal values for 43 of 43 analytes for the Roche Cobas 8000 chemistry analyzer and failed to have documentation to show the laboratory established test system performance specifications for the Sysmex CA-600 coagulation analyzer and the Cepheid GeneXpert CT/NG analyzer. Findings: 1. Review of the verification procedures for the Roche Cobas 8000 chemistry analyzer for Albumin, Alkaline phosphatase, Alanine aminotransferase, Amylase, Aspartate aminotransferase, Bilirubin, Calcium, Chloride, Cholesterol, Creatine kinase, Carbon dioxide, Creatinine, Glucose, High-density lipoprotein, Iron, Lactic acid, Lactate dehydrogenase, Lipase, Magnesium, Phosphorus, Potassium, Sodium, Total bilirubin, Total protein, Tryglycerides, Urea, Uric acid, Total iron-binding capacity, Free T3, Total T3, Total T4, Ferritin, Folate, Free T4, Thyroid stimulating hormone, Vitamin B12, Vitamin D, Beta HCG, Prostrate specific antigen, N-terminal pro b-type natruretic peptide, Troponin T, Creatine kinase MB, and Parathyroid hormone showed no verification of manufacturer's reference intervals with the laboratory's reported normal values. 2. The lack of documentation showed the the laboratory failed to establish performance specifications for accuracy, precision and reportable range for the test system CA-600 coagulation analyzer which tests for Prothombin Time and Activated Partial Thromboplastin Time. 3. The lack of documentation showed the laboratory failed to established performance specifications for accuracy, precision and reportable range for the test system Cepheid GeneXpert CT/NG analyzer which tests for Chlamydia trachomatis, Neisseria gonorrhoeae and Trichomonas. 4. Interview with the TS #1 and TS #2 on December 15, 2020 at 10:00 AM confirmed the laboratory failed to verify manufacturer's reference intervals for the Roche Cobas 8000 analyzer were appropriate for the laboratory's patient population and to establish performance characteristics for The CA-600 and Cepheid GeneXpert CT/NG analyzer after moving the lab to a new location and before reporting patient results.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

	This STANDARD is not met as evidenced by: Based on the lack of personnel training records for 2020, and interview with technical supervisor (TS) #2 confirmed the laboratory director (LD) failed to ensure testing personnel had documented initial training for the Roche Cobas 8000 chemistry analyzer prior to testing and reporting patient results. Approximately 1,130,000 patient test results have been reported since March 2020. Findings: 1. The lack of training records for 2020 revealed the LD failed to have initial training for 5 of 5 employees on the Roche Cobas 8000 chemistry analyzer brought on-line in March of 2020. 2. The interview with the TS #2 on December 15, 2020 at 10:40 AM confirmed, the LD failed to ensure each testing personnel had appropriate documented training for Roche Cobas 8000 chemistry analyzer before reporting patient test results. 3. Approximately 1,130,000 patient test results have been reported since March 2020.
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 review of performance evaluations for the year 2019 and interview with the technical supervisor (TS) #2, the TS failed to perform 5 of 5 performance evaluations for 2019. Findings: 1. Review of performance evaluations for 2019 showed the TS failed to evaluate 5 of 5 annual employee competencies. 2. Interview with the TS #2 on December 15, 2020 at 10:30 AM confirmed the TS failed to perform annual competencies for 2019.