Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 26D0446044	**(X3) Date Survey Completed** 01/30/2023
Name of Provider or Supplier Jefferson City Medical Group	**Street Address, City, State** 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**
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on review of proficiency testing records and interview with the technical supervisor (TS) #3, the laboratory failed to maintain a copy of all records for proficiency testing, including the signed attestation statement and the raw data for reporting of results for a minimum of two years. Findings: 1. Review of proficiency testing records showed the laboratory failed to provide a signed attestation form for the 3rd event for immunology in 2021. 2. Review of proficiency testing records showed the laboratory failed to provide raw data for reporting of results for the 2nd event for immunology 2021 for the following tests on the Cobas chemistry analyzer: 3. Review of records showed the laboratory failed to provide raw data for the 2nd event for miscellaneous chemistry in 2021 for the following tests on the Cobas chemistry analyzer: 3. Interview with TS #3 on January 24, 2023 at 12:00 pm confirmed the laboratory failed to maintain a copy of all records for proficiency testing, including the attestation statement and the raw data for a minimum of two years.

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 performance verification procedures for the Sysmex XN-1000 hematology analyzer and the Alcor Scientific iSED erythrocyte sedimentation rate (ESR) analyzer, review of laboratory pipettes, lack of maintenance documentation, review of quality control records, review of Roche Cobas e801 quality control (QC) records in the laboratory's LIS, review of Bio-Rad liquid assayed multiqual quality control package insert, lack of hematology records, review of laboratory procedures, Sysmex CA-600 analyzer quality control (QC), patient results and interviews, the laboratory failed to meet the condition of analytic systems. The laboratory failed to verify performance specifications prior to reporting patient test results (Refer to D5421); the laboratory failed to perform function checks on 13 of 13 laboratory pipettes in 2022 (Refer to D5435); the laboratory failed to ensure the quality control procedures were performed every 30 days for d-dimer, Clostridium difficile, and Chlamydia trachomatis and Neisseria gonorrhoeae (Refer to D5445); the laboratory failed to establish criteria for acceptability of control materials providing quantitative results for 26 of 26 analytes (Refer to 5469); the laboratory failed to document the quality of staining materials each day of use for manual differentials for 2021, 2022 and to date January 24, 2023 (Refer to D5473); the laboratory failed to include two levels of control material each 8 hours of operation for prothrombin time (PT) and partial thromboplastin time (PTT) for 77 of 79 testing days from October 1, 2022 to date January 23, 2023 (Refer to D5545).
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 Sysmex XN-1000 hematology analyzer and the Alcor Scientific iSED erythrocyte sedimentation rate (ESR) analyzer and interview with the technical supervisor (TS) #3, the laboratory failed to verify performance specifications prior to reporting patient test results. Findings: 1. Review of the performance specifications for the Sysmex XN-1000 hematology analyzer showed the laboratory failed to verify that the manufacturer's reference intervals (normal ranges) were appropriate for the laboratory's patient

	population for the analytes: red blood cell (RBC), hemoglobin, hematocrit, platelet, white blood cell (WBC) and differential prior to the beginning of patient testing in June 2021. 2. Review of patient results from June 2021 to date January 24, 2023 showed approximately 60,281 complete blood count (CBC) patient results were reported. 3. Review of the performance specifications for the Alcor Scientific iSED ESR analyzer showed the laboratory failed to verify that the manufacturer's reference intervals (normal ranges) were appropriate for the laboratory's patient population prior to the beginning of patient testing in February 2022. 4. Review of patient results from February 2022 to date January 24, 2023 showed approximately 5,219 ESR patient results were reported. 5. Interview with the TS #3 on January 24, 2023 at 11:30 AM confirmed the laboratory failed to verify performance specifications prior to reporting patient test results.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on review of laboratory, lack of maintenance documentation and interview with the technical supervisor (TS) #3, the laboratory failed to perform function checks on 13 of 13 laboratory pipettes in 2022. Findings: 1. Based on review of the laboratory showed 13 laboratory pipettes in use. 2. Lack of maintenance documentation showed the laboratory failed to perform functions checks in 2022 on the pipettes still in use below: #1000-1 MLA 200-1000uL due 08/31/2022 #503469 MLA 3ML due 08/31/2022 #700795 MLA 200-1000uL due 09/30/2022 #503650 MLA 2ML due 08/31/2022 #100-1 MLA 100uL due 09/30/2022 #5000-1 MLA 1-5ML due 08/31/2022 #400386 MLA 1-5ML due 08/31/2022 #702346 MLA 200-1000uL due 09/30/2022 #SEL-5000 MLA 2-5ML due 09/30/2022 #1(50-1) MLA 50uL due 09/30/2022 #803289 MLA 5uL due 08/31/2022 #1 MLA 50uL due 08/31/2022 #1(100-1) MLA 100uL due 08/31/2022 3. Interview with TS #3 on January 24, 2023 at 12:00 PM confirmed the laboratory failed to perform function checks on laboratory pipettes in 2022.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.

	This STANDARD is not met as evidenced by: Based on review of policy for test systems, quality control records, and interview with the technical supervisor (TS) #3, the laboratory failed to ensure the quality control procedure was performed every 30 days for d-dimer, Clostridium difficile, and Chlamydia trachomatis and Neisseria gonorrhoeae. Findings: 1. Review of the policy named "D-Dimer Procedure", states "external controls should be tested with each new lot or shipment of test devices and or every 30 days". 2. Review of d-dimer quality control records showed that the laboratory failed to perform quality controls every thirty days during 2021 and 2022 for the following dates: Level /1 11/23/21 to 12/30 /2021 - 37 days 4/1/22 to 5/2/22 - 31 days 5/13/22 to 6/14/22 - 32 days 6/14/22 to 7/18 /22 - 34 days 7/18/22 to 9/19/22 - 63 days 9/19/22 to 11/02/22 - 44 days 12/15/22 to 01 /16/23 - 32 days Level 2 10/4/21 to 11/19/21 - 46 days 11/23/21 to 12/30/21 - 37 days 4/1/22 to 5/2/22 - 31 days 5/13/22 to 6/14/22 - 32 days 6/14/22 to 7/18/22 - 34 days 7 /18/22 to 9/19/22 - 63 days 9/19/22 to 11/02/22 - 44 days 3. Review of patient results from January 2021 to date January 24, 2023 showed approximately 681 d-dimer patient results were reported. 4. Review of the policy named "Clostridium Difficile", states "external controls are run with every new shipment and each new lot of test cartridges and at least every 30 days". 5. Review of Clostridium difficile quality control records showed that the laboratory failed to perform quality controls every thirty days during 2021 and 2022 for the following dates: 2/10/21 to 3/17/21 - 35 days 3/17/22 to 4/21/21 - 35 days 5/21/21 to 7/6/21 - 34 days 11/23/21 to 1/24/23 - 63 days 3/2/22 to 4/5/22 - 34 days 4/28/22 to 6/1/22 - 34 days 6/1/22 to 7/14/22 - 43 days 7/14 /22 to 8/26/22 - 43 days 9/16/22 to 10/19/22 - 33 days 10/19/22 to 11/21/22 - 33 days 11/21/22 to 12/27/22 - 36 days 6. Review of patient results from January 2021 to date January 24, 2023 showed approximately 885 Clostridium difficile patient results were reported. 7. Review of the policy named "CT/NG by PCR", states "external controls are run with every new shipment and each new lot of test cartridges and at least every 30 days". 8. Review of Chlamydia trachomatis and Neisseria gonorrhoeae quality control records showed that the laboratory failed to perform quality controls every thirty days during 2021 and 2022 for the following dates: 3/10/21 to 4/30/21 - 51 days 5/13/21 to 6/28/21 - 46 days 7/21/21 to 8/23/21 - 33 days 10/13/21 to 11/17/21 - 35 days 12/23/21 to 1/24/22 - 32 days 2/28/22 to 4/5/22 - 36 days 4/28/22 to 6/1/22 - 34 days 6/29/22 to 8/3/22 - 35 days 8/16/22 to 10/19/22 - 64 days 10/19/22 to 11/22/22 - 34 days 11/22/22 to 12/27/22 - 35 days 9. Review of patient results from January 2021 to date January 24, 2023 showed approximately 3,459 Chlamydia trachomatis and 3,458 Neisseria gonorrhoeae patient results were reported. 10. Interview with the TS #3 on January 24, 2023 at 1:00 PM confirmed the laboratory failed to show the quality control procedure was performed every 30 days for D-dimer, Clostridium difficile, and Chlamydia trachomatis and Neisseria gonorrhoeae.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the

	laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on interview with technical supervisor (TS) #3, review of Roche Cobas e801 quality control (QC) records in the laboratory's LIS, review of Bio-Rad liquid assayed multiqual quality control package insert, the laboratory failed to establish criteria for acceptability of control materials providing quantitative results for 26 of 26 analytes. Findings: 1. Interview with TS #3 confirmed the laboratory uses Bio-Rad liquid assayed multiqual quality control (QC) for their Roche Cobas e801. The laboratory started using Bio-Rad assayed multiqual , lot # 45930 on December 1, 2022. 2. Review of the Roche Cobas e801 QC records showed the laboratory did not establish and define statistical parameter criteria (mean and standard deviations) for acceptability of quantitative QC results reported on the chemistry analyzer for the analytes: aspartate aminotransferase, alanine aminotransferase, albumin, alkaline phosphate, calcium, cholesterol, chloride, creatinine, creatinine kinase, direct bilirubin, CO_2, gamma glutamyltransferase (GGT), glucose, iron, lactate dehydrogenase (LDH), lipase, magnesium, phosphorus, potassium, sodium, total bilirubin, total protein, triglyceride, urea, and uric acid. 3. Interview with the TS #3 on January 24, 2023 at 12:00 PM, confirmed the laboratory failed to establish criteria for acceptability of chemistry control materials providing quantitative results.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on lack of hematology records and interview with the technical supervisor (TS) #3, the laboratory failed to document the quality of staining materials each day of use for manual differentials for 2021, 2022 and to date January 24, 2023. Findings: 1. Lack of hematology records showed the laboratory failed to document the quality of staining materials each day of use for manual differentials in 2021, 2022 and to date January 24, 2023. 2. Review of patient results from January 2021 to date January 24, 2023 showed approximately 2,695 manual differential patient results were reported. 3. Interview with TS #3 on January 24, 2023 at 12:00 PM confirmed the laboratory failed to document the quality of the manual differential stain each day of use.
D5545	HEMATOLOGY CFR(s): 493.1269(b)(d) (b) For all nonmanual coagulation test systems, the laboratory must include two levels of control material each 8 hours of operation and each time a reagent is changed. (d) The laboratory must document all control procedures performed, as specified in this section.

	This STANDARD is not met as evidenced by: Based on review of laboratory procedures, Sysmex CA-600 analyzer quality control (QC), patient results and interview with the technical supervisor (TS) #3, the laboratory failed to include two levels of control material each 8 hours of operation for prothrombin time (PT) and partial thromboplastin time (PTT) for 77 of 79 testing days from October 1, 2022 to date January 23, 2023. Findings: 1. Review of laboratory procedures "Prothrombin Time" and "Partial Thromboplastin Time" states, "Run Coagulation Controls level 1 and 3 at the beginning of the shift and again in the afternoon, preferably early afternoon". 2. Review of Sysmex CA-600 analyzer QC from October 1, 2022 to date January 23, 2023 showed QC was not performed every 8 hours for 77 of 79 testing days. 3. Review of patient results showed approximately 64 patient PT results and 5 PTT patient results were released when QC was not performed. 4. Interview with the TS #3 on January 24, 2023 at 11:30 AM confirmed the laboratory failed to perform two levels of PT and PTT QC each 8 hours of operation.
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 employee competencies and interview with the technical supervisor (TS) #3, the TS failed to perform annual performance evaluations for 2 of 3 testing personnel (TP). Findings: 1. Review of employee performance evaluations showed the TS failed to perform the annual performance evaluations for TP #1 in 2022 and TP #2 for 2021 and 2022. 2. Interview with TS #3 on January 24 , 2023 at 12:00 pm confirmed that the TS failed to perform the annual performance evaluations for TP #1 and TP #2.