Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	26D0446044	03/04/2025
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
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of the coagulation procedure manual, reference range verification study for prothrombin time reagent (Innovin) in use from July 23, 2024 to date March 4, 2025, prothrombin time test report, patient test volumes and interview with the technical supervisor, the laboratory failed to follow the written procedure to monitor and assess results of prothrombin time reference range studies. Findings: 1. Coagulation procedure section VIII, "Interpretation of Results" dated January 2018 states, " The normal patient reference range is calculated each time a new lot # of reagent is received." 2. Review of the reference range verification study for prothrombin time testing showed the laboratory calculated a patient normal range of 10.59-11.14 seconds for Innovin lot # 564652. The 21 patient reference range study approved July 9, 2024 showed 100% of patient results exceeded the reference range in use. 3. Review of patient test report #258705 resulted March 4, 2025 at 08:56 AM showed a normal prothrombin time reference range of 9.0-11.4 seconds. 4. The laboratory performed 825 protime tests since reagent was placed into use on July 23, 2024. 5. Interview on March 4, 2025 at 11:00 AM the technical supervisor agreed the laboratory failed to follow procedures when introducing a new lot of prothrombin time reagent.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)

	(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on the lack of documentation and interview with testing personnel #4, the laboratory failed to define criteria for room temperature, refrigerator temperature and humidity in the hematology testing room of the oncology clinic. The laboratory did not document conditions for essential storage and testing environment since January 30, 2023. Findings: 1. The laboratory did not have documentation to show that staff monitored the room temperature, refrigerator temperature used to store quality control (QC) and humidity of the hematology testing room in the oncology clinic. 2. Interview with testing personnel #4 on March 4, 2025 at 10:45 AM confirmed, the laboratory failed to define criteria for storage and testing environment and document those conditions.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on observation of laboratory refrigerator, and interview with the technical supervisor (TS), the laboratory failed to ensure laboratory chemistry calibrators were not used when they had exceeded their expiration date. Findings: 1. Observation of laboratory refrigerator showed chemistry calibrators FT3 111 lot # (10)74633405 expired January 31, 2025 and still in use. 2. Interview with the TS on March 4, 2025 at 10:00 AM confirmed the laboratory failed to ensure laboratory chemistry calibrators were not used when they had exceeded their expiration date.
D5427	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(c) (c) Documentation. The laboratory must document all activities specified in this section. This STANDARD is not met as evidenced by: Based on the lack of Activated Partial Thromboplastin (APTT) normal range verification records for reagent in use, procedure manual, patient testing volume and interview with the technical supervisor, the laboratory failed to have documentation of a normal range patient study for Actin and Calcium Choride reagents in use for testing March 4, 2025. Findings: 1. No documentation was available to show the laboratory performed a normal range patient study for reagents in use for APTT testing; Actin,

	lot # 562766 placed in use March 2024 and Calcium Chloride lot #56393528 placed in use January 14, 2025. 2. The procedure manual states, "Normal range for Partial Thromboplastin time has been set and verified by a normal range study on each new lot of reagent." 3. The laboratory performed 125 patient APTT tests since March 2024. 4. Interview with the technical supervisor on March 4, 2025 at 09:50 AM confirmed, the laboratory failed to provide documentation of an APTT patient normal range study for reagents in use.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3)-- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of 2023, 2024 and 2025 calibration records for the Roche Cobas chemistry analyzer and interview with the technical supervisor (TS), the laboratory failed to perform calibration verification procedures at least once every six months that included at least a minimal value, a mid-point value, and a maximum value near the upper limit to verify the laboratory's reportable range in 2023 and 2024 for 3 of 35 analytes. Findings: 1. Review of the Roche Cobas chemistry analyzer calibration records for 2023 and 2024 showed no calibration every six months that included at least a minimal value, a mid-point value, and a maximum value near the upper limit to verify the laboratory's reportable range for the analytes: sodium, potassium, and chloride. 2. Interview with the TS on March 4, 2025, at 11:00 AM confirmed the laboratory failed to perform calibration verification procedures at least once every six months for sodium, potassium, and chloride.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) (d)(3)(ii) Each qualitative procedure, include a negative and positive control material; This STANDARD is not met as evidenced by: Based on review of the Cardinal Health hCG Combo Rapid Test quality control (QC), and interview with the technical supervisor (TS), the laboratory failed to perform a negative and positive control material each day of serum pregnancy patient testing

	from March 2023 to date March 4, 2025. Findings: 1. Review of Cardinal Health hCG Combo Rapid QC showed no documentation of a negative and positive control material each day of patient testing from March 2023 to date March 4, 2025. The laboratory could not provide the number of serum pregnancy tests performed. 2. Interview with TS on March 4, 2025 at 10:30 AM confirmed the laboratory failed to perform a negative and positive control material each day of patient testing for the Cardinal Health hCG Combo Rapid Test for serum pregnancy.
D5807	TEST REPORT CFR(s): 493.1291(d) (d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on review of two of two selected patient test reports from March 4, 2025, laboratory procedure manual and interview with the general supervisor, the laboratory failed to ensure pertinent normal values as determined by the laboratory were available for interpretation for activated partial thromboplastin time (APTT) and serum calcium. Findings: 1. The difference between normal values included on two selected patient test reports from March 4 , 2025 and those included in the approved procedure manual are as follows: -APTT normal values included on test reports (22-32.8 seconds) -APTT normal values stated in the approved procedure manual (23-32.8 seconds) -serum calcium normal range (adult 60-90 years) stated in approved procedure manual (8.8-10.2 mg/dl) -serum calcium normal range (adult age 69) stated on test report 44885 (8-6-10.3 mg) 2. Interview with the general supervisor on March 4, 2025 at 11:30 AM confirmed the discrepant normal values for serum calcium and APTT tests.
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) (b)(9) Thereafter, evaluations must be performed at least annually unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individuals 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 personnel records and interview with the technical supervisor (TS), the TS failed to evaluate and document competency/performance for one of five testing personnel (TP) at least annually during 2023, 2024 and to date March 4, 2025. Findings: 1. Review of personnel records showed the TS did not evaluate competency /performance for TP #4 performing patient testing during 2023, 2024 and to date March 4, 2025. 2. Interview with TS on March 4, 2025 at 11:00 AM, confirmed competency/performance evaluations were not conducted at least annually for TP #4.