Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	26D0441699	11/30/2023
Name of Provider or Supplier	**Street Address, City, State**	
Putnam County Memorial Hospital	1926 Oak Street, Unionville, 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 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 iStat procedure, observation of iStat at nurses station and interview with the general supervisor (GS), the laboratory failed to follow the iStat procedure for room temperature and humidity requirements for 331 of 331 days in 2023. Findings: 1. Review of iStat procedure states "operating temperature 15-40 degrees Celsius; relative humidity 90 percent non-condensing". 2. Observation of iStat at the nurses station showed no room temperature or humidity documented from January 2023 to date November 28, 2023. 3. Interview with the GS on November 28, 2023 at 10:30 AM confirmed the laboratory failed to follow the iStat procedure and document humidity and room temperature at the nurses station. 44735 Based on review of laboratory procedures, refrigerator temperature logs, humidity logs, and interview with the general supervisor (GS), the laboratory personnel failed to follow the established general maintenance procedure for 4 of 332 testing days in 2023. Findings: 1. Review of the laboratory procedure "General Maintenance," states, "Refrigerators/Freezers: Record temperatures on a daily basis." 2. Review of the laboratory's refrigerator temperature logs showed the laboratory personnel failed to record the refrigerator temperature on April 2, 2023, July 23, 2023 and September 30, 2023. 3. Review of the laboratory procedure "General Maintenance" states, "Read and record each day of operation the room temperature and humidity for the laboratory." 4. Review of the laboratory's humidity logs showed the laboratory personnel failed to

	record the humidity for the laboratory on November 12, 2023. 5. Interview with the GS on November 28, 2023 at 10:00 AM confirmed the laboratory personnel failed to follow the established general maintenance procedure.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(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: (1) Water quality. (2) Temperature. (3) Humidity. (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 observation of the freezer, review of laboratory temperature logs from January 2023 to date November 28, 2023 and interview with the general supervisor (GS), the laboratory failed to follow manufacturer's instructions for acceptable storage temperature for the chemistry quality control stored in the freezer for 79 of 331 testing days in 2023. Findings: 1. Observation of freezer chemistry quality control stated store at "-20 to -70 degrees Celsius" for the following: -4 bottles BioRad Liquichek cardiac markers plus control LT lot # 67691 expiration 8/31/25 -2 bottles BioRad Liquichek specialty Immunoassay control lot # 64941 expiration 4/30/24 -12 bottles BioRad Liquichek cardiac markers plus control LT lot # 67693 expiration 8/31/25 2. Review of laboratory temperature logs from January 2023 to date November 28, 2023 showed freezer with an unacceptable temperature range for 79 testing days. 3. Interview with the GS on November 28, 2023, 2023 at 10:00 AM confirmed the laboratory failed to follow manufacturer's instructions for acceptable storage temperature for chemistry quality control stored in the freezer. 47802 Based on review of policies, review of temperature logs, and interview with the general supervisor (GS), the laboratory failed to document the temperature and revaluations per minute (RPM) for the MTS incubator and centrifuge workstation. Findings: 1. Review of the policy titled Antibody Screen (Selectogen I & II) states: -Incubate at 37+/- 2C for 15 minutes -Centrifuge the gel card at the pre-set conditions of 895 +/- 25 RPMs for 10 minutes 2. Review of the blood bank temperature and maintenance logs from April 1, 2022 to date November 28, 2023 showed no documentation of temperature and RPM for the MTS incubator and centrifuge workstation. 3. Interview with the GS on November 28, 2023 at 11:30 AM confirmed the laboratory failed to document temperature and RPM for the MTS incubator and centrifuge workstation.
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 Ortho Diagnostics Vitros 5600 chemistry analyzer, patient results, and interview with the general supervisor (GS), the laboratory failed to verify performance specifications prior to reporting patient test results. Findings: 1. Review of the performance specifications for the Ortho Diagnostics Vitros 5600 chemistry 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: albumin, alcohol, amylase, alkaline phosphatase, alanine transaminase (ALT), aspartate aminotransferase (AST), direct bilirubin, indirect bilirubin, urea nitrogen (BUN), calcium, creatine kinase, chloride, cholesterol, carbon dioxide (CO2), creatinine, direct low-density lipoprotein (DLDL), glucose, potassium, lactate dehydrogenase (LDH), magnesium, sodium, phosphorus, total bilirubin, total protein, triglycerides, uric acid, lactic acid, brain natriuretic peptide (BNP2), troponin I, creatine kinase MB (CKMB), thyroid-stimulating hormone (TSH), and free thyroxine (Free T3) prior to the beginning of patient testing in June 2022. 2. Review of patient results showed the laboratory performs approximately 45,332 chemistry tests per year. 3. Interview with the GS on November 28, 2023 at 10:00 AM confirmed the laboratory failed to verify performance specifications prior to reporting patient test results.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of personnel records and interview with testing personnel (TP) #29, the technical consultant (TC) failed to evaluate and document the performance of four of four TP at least semiannually during the first year the individual tests patient specimens in 2023. Findings: 1. Review of performance evaluations showed the TC failed to perform the semiannual competency evaluations for TP #22, TP #25, TP #28 and TP #32. 2. Interview with TP #29 on November 28, 2023 at 11:30 AM, confirmed the TC failed to evaluate and document the performance of four TP at least semiannually during the first year the individual tests patient specimens.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on review of performance evaluations and interview with the testing personnel (TP) #29, the technical consultant (TC) failed to evaluate and document the annual performance evaluation for two of thirty-two TP. Findings: 1. Review of performance evaluations showed the following: -No annual performance evaluation for TP #18 and TP #28 in 2023 -No annual performance evaluation for TP #18 in 2022. 2. Interview

	with TP #29 on November 28, 2023 at 11:20 AM confirmed the TC failed to evaluate and document the annual performance evaluations for two testing personnel.