Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	26D0441699	04/24/2018
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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of competency procedure, blood gas competencies and interview with the general supervisor, the laboratory failed to follow competency policy for 23 of 23 testing personnel for blood gases in 2017 and to date April 24, 2018. There was no documentation of direct observations for competency with the laboratory director who is also the technical supervisor's approval. Findings: 1. Review of "Annual Orientation and competency of laboratory staff" policy states "direct observations of routine patient test performance including patient preparation, if applicable, specimen handling, processing and testing". No documentation of direct observation for 23 testing personnel for blood gases. 2. Review of "Annual orientation and competency of laboratory staff" policy states "testing personnel for each test the the individual is approved by the laboratory director". No documentation of laboratory director approval for 23 blood gas testing personnel competencies. 3. Interview with testing personnel #1 for blood gases on April 24, 2018 at 1:30 PM confirmed the laboratory failed to follow policy for blood gas testing personnel competencies.
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 toxicology procedure manual, observation of toxicology centrifuge and interview with the testing personnel #2, the laboratory failed to follow instructions for urine toxicology testing. Findings: 1. Review of the toxicology procedure manual showed the laboratory must centrifuge urine for urine toxicology confirmation testing at 13300 revolutions per minute (RPM). 2. Observation of the toxicology centrifuge revealed, the centrifuge spins at 14851 RPM. 3. Interview with the testing personnel #2 on April 24, 2018 at 1:00 PM confirmed, the laboratory failed to centrifuge urine at the speed stated in the procedure manual.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of the hematology procedure manual, patient records for 2018, and interview with the general supervisor, the procedure manual failed to include a step by step procedure for using blue top tubes (sodium citrate anticoagulant) for complete blood counts (CBCs) on patients exhibiting platelet clumping in purple top (EDTA) tubes. Findings: 1. Review of the hematology procedure manual revealed the manual did not include a step by step procedure for using blue top tubes for CBC testing. Use of blue top tubes for CBC testing requires a calculation factor to compensate for the volume of sodium citrate anticoagulant in the blood specimen tube. 2. Review of patient records for 2018 showed the laboratory tested one patient using a blue top tube to obtain CBC results. 3. Interview with the general supervisor on April 24, 2018 at 2: 45 PM confirmed, the procedure manual did not include a procedure for the use of blue top tubes on patients that exhibit platelet clumping. 35554 Based on review of the toxicology manual revealed and interview with the general supervisor on April 24, 2018 at 2:00 PM confirmed the laboratory failed to include reference intervals(cutoff values) for the Shimadzu LCMS 8030, 8050 and the AU 400 for urine toxicology testing.
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 review of the blood bank procedure manual and interview with the general supervisor on April 24, 2018 at 2:45 PM confirmed the current laboratory director failed to approve, sign and date the blood bank procedures. 38475 Based on review of the respiratory therapy blood gas procedure manual and interview with testing personnel # 1 on April 24, 2018 at 1:30 PM confirmed, the laboratory director failed to approve, sign and date the blood gas procedure manual.
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 review of manufacturer's instructions, documentation of freezer temperatures and observation of Vitros calibrator and verifier material stored in the freezer, and interview with the general supervisor, the laboratory failed to follow the manufacturer's instructions for storage of calibrator and verifier material for 113 of 114 testing days since January 1, 2018 through April 24, 2018. . Findings: 1. Review of the manufacturer's instructions for Vitros calibrator and verifier showed calibrators must be stored at less than or equal to minus 18 degrees Celsius (C). 2. Review of the laboratory's temperature chart showed a defined acceptable range of minus 10 degrees C to minus 20 degrees C. 113 of 114 testing days failed to meet the manufacturer's required temperature of equal to or less than minus 18 degree C. 3. Observation of the laboratory freezer showed 4 boxes of Vitros verifier I(lot# W52Q), 1 box Vitros verifier II(lot#A6018), 2 boxes of calibrator I(lot #0137), 1 box Vitros calibrator II(lot 0267), 1 box Vitros calibrator III(lot# 0357), 1 box Vitros calibrator IV(lot#0437), 4 boxes cholesterol calibrator II, 7 boxes glucose calibrator I, 4 boxes AST calibrator III, 4 boxes creatinine calibrator I, 4 boxes LDH calibrator III, 1 box magnesium, 4 boxes triglycerides calibrator II. 4. Interview with the general supervisor on April 24, 2018 at 1:00 PM confirmed the laboratory failed to properly monitor the freezer and store calibrator and verifier materials per manufacturer's instructions.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer

	must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on review of manufacturer's manual, procedure manual, verification of performance specifications, and interview with testing personnel #2, the laboratory failed to provide documentation of reference intervals for 70 of 70 analytes and failed to prove precision for the analytes Nalaxone, Zopicione and precision and analytical specificity for the analyte Temazepam for a modified test system, Shimadzu LCMS 8050, 8030 for toxicology testing labeled "For research use only. Not for use in diagnostic procedures." Findings: 1. Review of the Shimadzu LCMS 8050, 8030 manual for toxicology testing revealed "the instrumentation is intended for research use only." 2. Review of the procedure manual for the acceptable coefficient of variation(CV) for the performance characteristic of precision showed "the value of CV % could not exceed +/- 25 %." Review of the performance characteristic of analytical specificity showed "a difference within 30% is acceptable." 3. Review of the performance specification documentation for precision for the analyte Nalaxone showed a CV of 32.5% for the low concentration and 25.9% for the middle level. Review of the performance specification documentation for precision for the analyte Temazepam showed a CV of 26.6% for the low concentration. Review of the performance specification documentation for precision for the analyte Zopicione showed a CV of 26.2% for the low concentration. 4. Review of the performance specification documentation for analytical specificity for the analyte Temazepam showed a CV of 37.3%. 5. Review of the laboratory's validation reports for performance specifications of the Shimadzu LCMS 8050, 8030 instrumentation revealed the laboratory failed to verify reference intervals(normal values) for 70 of 70 analytes. 6. Interview with the testing personnel #2 on April 24, 2018 at 1:00 PM confirmed the laboratory failed to provide the performance specifications for analytical specificity for Temazepam and precision for Nalaxone, Temazepam, and Zopicione and reference intervals before using an off label modified kit system.
D5537	ROUTINE CHEMISTRY CFR(s): 493.1267(b)(d) For blood gas analyses, the laboratory must perform the following: (b) Test one sample of control material each 8 hours of testing using a combination of control materials that include both low and high values on each day of testing. (d) Document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of blood gas quality control (QC) and interview with testing personnel #1 the laboratory failed to perform one sample of control material each 8 hours of testing for January 2017 to present day April 24, 2018.. Findings: 1. Review of blood gas QC showed laboratory failed to test one sample of control material each 8 hours of testing using a combination of control materials that include both low and high values on each day of patient testing for January 2017 to present day April 24, 2018. 2. Interview with testing personnel #1 on April 24, 2018 confirmed the

	laboratory failed to perform one sample of blood gas control material each 8 hours of patient testing for January 2017 to present day April 24, 2018.
D5807	TEST REPORT CFR(s): 493.1291(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 patient chemistry test reports for 2018, the chemistry 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. Chemistry normal values included on test reports for five of eight selected analytes differed from those included in the approved chemistry procedure manual. Findings: 1. The differences between chemistry normal values included on patient test reports and those included in the procedure manual approved by the director are as follows: Normal values included on patient test reports: Potassium (K) (3.6-5.0 mmol/L) Glucose (75-110 mg/dl) Creatinine (0.8- 1.5 mg/dl) male Urine Creatinine (20-300 mg/dl) pH (3.9-9.1 U/L) Normal values included in the approved procedure manual: Potassium (K) (3.5-5.1 mmol/L) Glucose (74-106 mg/dl) Creatinine (0.66- 1.25 mg/dl) male Urine Creatinine (20-200 mg/dl) pH (5.0-8.0 U/L) 2. Interview with the general supervisor on April 24, 2018 at 2:45 PM confirmed the normal values determined by the laboratory and approved by the director differed from those included on the test reports.
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 competencies and interview with the general supervisor on April 24, 2018 at 12:15 PM confirmed the technical supervisor failed to evaluate and document annual competency on two (#1 and #6) of seven testing personnel in 2017.