Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	26D0441699	09/04/2019
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 blood bank procedure manual, patient records and blood bank quality control (QC) for August 2019 and interview with the general supervisor, the laboratory failed to follow the manual for performing blood bank QC. Findings: 1. The blood bank procedure manual states, "Blood Bank Quality Control in this laboratory is to be processed on the day a Blood Bank Procedure is requested." 2. Review of patient records revealed the laboratory performed a forward type, reverse type, antibody screen and compatibility test on patient (G) on August 19, 2019. Patient records showed patient (G) received two units of packed red blood cells on August 19, 2019. The laboratory did not have documentation to show blood bank QC was performed / processed on August 19, 2019. 3. Interview on September 4, 2019 at 11:00 AM, the general supervisor confirmed the laboratory did not perform QC on the day the procedure was requested. Interview confirmed the laboratory failed to follow the written blood bank QC procedure.
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 laboratory procedure manuals in use September 4, 2019 and interview with the general supervisor, the procedure manuals failed to include reference intervals (normal values) for white blood cell (WBC) auto-differential, WBC manual differential and urine microscopic examinations. Findings: 1. The hematology procedure manual did not include normal values for WBC auto-differential and WBC manual differential. 2. The urinalysis procedure manual did not include normal values for urine microscopic examination (urine sediment). 3. Interview with the general supervisor on September 4, 2019 at 11:00 AM confirmed, the procedure manuals did not include normal values for WBC auto-differential, WBC manual differential and urine microscopic examinations.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the procedure manual, quality control (QC) and patient logs for August 1, 2019 to date September 4, 2019 and interview with the general supervisor, the laboratory failed to perform a negative and positive control for MedTox urine drug screen testing each day of patient testing. Findings: 1. Review of the procedure for urine toxicology screening showed "the use of positive (commercial control) and negative (distilled water) will be tested each day of testing." 2. No QC was performed at least once a day for August 24, 25, 26, and September 3, 2019. 3. Review of patient logs showed 4 patients were reported out for MedTox urine drug screen for August 24, 25, 26, September 3, 2019. 4. Interview with general supervisor on September 4, 2019 at 11:30 AM confirmed the laboratory and failed to perform a negative and positive control material each day of testing.
D5801	TEST REPORT CFR(s): 493.1291(a)

	The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Based on review of patient chemistry instrument (Vitros 350) records/ patient test reports for September 4, 2019 and interview with the general supervisor on September 4, 2019, the laboratory failed to have an adequate manual or electronic system in place to ensure test results are reliably sent from the point of data entry (interfaced or manual entry) to final report destination. Findings: 1. Review of instrument printouts revealed the chemistry instrument performed an ALT test on patient (B) September 4, 2019. 2. Review of final destination test report revealed the test report did not include the ALT result obtained on the chemistry instrument September 4, 2019. 3. The laboratory could not demonstrate the results of the ALT were sent (interfaced) to the laboratory information system (LIS) or have a system in place to enter the result manually. 4. Interview with the general supervisor on September 4, 2019 at 11:00 AM confirmed the laboratory failed to have an adequate system to ensure all test results are sent from point of data entry to the final report destination.
D6098	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(8) The laboratory director must ensure that reports of test results include pertinent information required for interpretation. This STANDARD is not met as evidenced by: Based on review of patient chemistry test reports generated on September 4, 2019, reference intervals (normal values) included in the procedure manual and interview with the general supervisor, the laboratory director failed to ensure pertinent normal values as determined by the laboratory were available for interpretation. Chemistry normal values included on two of two selected test reports 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: Glucose (75-110 mg/dl) Creatinine (0.52-1.04 mg/dl) adult ALT (21-72 U/L) adult male BUN (9-20 mg/dl) adult male Normal values included in the approved procedure manual: Glucose (74-106 mg/dl) Creatinine (0.66-1.25 mg/dl) maleALT (less than 50 U/L) adult male BUN (7-17 mg/dl) adult 2. Interview with the general supervisor on September 4, 2019 at 10:00 AM confirmed the normal values determined by the laboratory and approved by the laboratory director differed from those included on the test reports.