Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	26D0441699	03/19/2026
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) 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 procedures, and interview with the general supervisor (GS) #1, the laboratory failed to provide procedures for alarm checks and patient history in immunohematology. Findings: 1. Review of procedures revealed no alarm check and patient history procedures. 2. Interview with GS #1 on March 17, 2026 at 11:00 AM confirmed the laboratory failed to provide procedures for alarm checks and patient history in immunohematology.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) (d)(3)(i) Each quantitative procedure, include two control materials of different concentrations; This STANDARD is not met as evidenced by: Based on review of the Vitros 5600 chemistry analyzer quality control (QC) records for February 2026, patient results, and interview with the general supervisor (GS) #1, the laboratory failed to include two acceptable control materials of different concentrations for carbon dioxide (ECO2) for 5 of 28 patient testing days. Findings: 1. Review of the Vitros 5600 chemistry analyzer QC records for February 2026 showed two acceptable levels of ECO2 QC was not performed on: February 7, 2026 February

	8, 2026 February 9, 2026 February 12, 2026 February 17, 2026 2. The laboratory was unable to provide the number of patient's ECO2 results were reported in February 2026. 3. Interview with the GS #1 on March 17, 2026, at 10:15 AM confirmed the laboratory failed to include two control materials each day of patient testing for ECO2.
D5555	IMMUNOHEMATOLOGY CFR(s): 493.1271(c)(f) (c) Blood shall be stored in a clean and orderly environment in a manner to prevent mix-ups. Expired blood must not be in the routine inventory. Unacceptable units must be segregated from routine inventory. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. This STANDARD is not met as evidenced by: Based on review of blood bank alarm check log, and interview with the general supervisor (GS) #1, the laboratory failed to perform blood bank refrigerator alarm inspections quarterly from January 2024 to date March 17, 2026. Findings: 1. Review of the laboratory's blood bank alarm check log showed no blood bank refrigerator alarm inspections were completed from January 2024 to date March 17, 2026. 3. Interview with the GS #1 on March 17, 2026, at 11:00 AM confirmed, the laboratory failed to perform blood bank refrigerator alarm inspections quarterly in 2024 and to date March 17, 2026.
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 Siemens CA-660 Reference Interval procedure, review of 2 of 2 patient reports, and interview with the general supervisor (GS) #1, the laboratory failed to ensure the reference intervals or normal values on the patient report matched the procedure. Findings: 1. Review of "Siemens CA-660 Reference Interval" procedure showed: aPTT (secs) 24.5-32.8 2. Review of the patient report showed: aPTT (secs) 21.62-35.78 3. Interview with the GS #1 on March 17, 2026 at 11:00 AM confirmed the normal values on the patient report did not match the procedure.
D6101	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(11) (e)(11) Employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart; This STANDARD is not met as evidenced by:

	Based on review of personnel records and interview with the general supervisor (GS) #1, the laboratory director failed to employ a sufficient number of laboratory personnel with the appropriate training to accurately perform the volume of non-waived testing performed. Findings: 1. Review of personnel records on March 17, 2026 showed the laboratory had three full-time, appropriately trained testing personnel for immunohematology high complexity testing in a laboratory that is open 24 hours a day, 365 days a year. The laboratory performs approximately 59,326 laboratory tests per year. 2. Interview with the general supervisor (GS) #1 on March 17, 2026 at 12:00 PM confirmed the laboratory director failed to employ a sufficient number of laboratory personnel with the appropriate training to accurately perform the volume of non-waived testing performed.
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on review of the performance verification procedures for the Siemens CA-660 coagulation analyzer, review of training and competency documents and interview with the general supervisor (GS) #1, the technical supervisor (TS) failed to identify and document initial training needs for two of five testing personnel (TP) performing coagulation testing. Findings: 1. Review of the performance verification procedures for the Siemens CA-660 coagulation analyzer showed the laboratory began patient testing on September 12, 2024. 2. Review of training and competency documents showed the laboratory could not provide documentation for initial training and competency for TP #3 and TP #4 for the Siemens CA-660 coagulation analyzer. 3. Interview with the GS #1 on March 17, 2026 at 11:30 AM, confirmed the technical supervisor failed to identify and document training needs for two TP performing testing on the Siemens CA-660 coagulation analyzer.