Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	26D0652220	05/12/2026
Name of Provider or Supplier	**Street Address, City, State**	
Ray County Memorial Hospital	904 Wollard Blvd, Richmond, 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 laboratory procedures, gram stain quality control (QC) records from January 2026 to date May 12, 2026, patient results, and interview with the technical supervisor (TS) #1, the laboratory failed to follow the written procedure for gram stains for 117 of 132 days in 2026. Findings: 1. Review of laboratory procedure "Gram Stain" states "Check the Gram stain reagents in use at least once daily to make sure they are staining properly". 2. Review of gram stain QC records from January 2026 to date May 12, 2026 showed no gram stain QC documented on 117 days. 3. Review of patient results showed the laboratory performed 3 gram stains from January 2026 to date May 12, 2026. 4. Interview with the technical supervisor (TS) #1 on May 12, 2026 at 11:00 AM confirmed the laboratory failed to follow the written procedure for gram stains.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(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. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of

	results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(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. (b)(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 immunohematology procedures, and interview with the technical supervisor (TS) #1, the laboratory failed to provide step-by-step procedures for transfusion reaction and emergency release of uncrossmatched blood in immunohematology. Findings: 1. Review of procedures revealed transfusion reaction and emergency release of uncrossmatched blood procedures that did not match the current SafeTrace immunohematology laboratory information system (LIS) process. 2. Interview with TS #1 on May 12, 2026 at 10:30 AM stated "We went live with SafeTrace in February 2025". 3. Interview with TS #1 on May 12, 2026 at 12:00 PM confirmed the laboratory failed to provide step-by-step procedures for transfusion reaction and emergency release of uncrossmatched blood in immunohematology.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) (a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on observation of Hema-Quik hematology stain, review of Protocol Hema-Quik stain solution package insert, and patient results, and interview with the technical supervisor (TS) #1, the laboratory failed to follow manufacturer's instructions for hematology stain performance specifications. Findings: 1. Observation of Hema-Quik hematology stain in use showed dried Hema-Quik stain solution in the container with no lid that had been evaporated. 2. Review of Protocol Hema-Quik stain solution package insert stated "Indications of Deterioration: The presence of excessive precipitate in stain solution or on stained slides and inadequate differentiation of cell types may indicate deterioration". 3. Review of manual differential patient results showed approximately 83 manual differentials patient results reported annually. 4. Interview with the TS #1 on May 12, 2026 at 10:30 AM confirmed the laboratory failed to to follow manufacturer's instructions for hematology stain performance specifications.
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 supplies during the laboratory tour, review of Becton Dickinson (BD) BBL DrySlide Oxidase and Indole package inserts and patient results and interview with the technical supervisor (TS) #1, the laboratory failed to ensure laboratory supplies were not used when they had exceeded their expiration date. Findings: 1. Observation of laboratory supplies during the laboratory tour on May 12, 2026, at 9:30 AM, showed one package of BD BBL DrySlide Oxidase Lot # 5133725 opened on April 12, 2026 and one package of BD BBL DrySlide Indole Lot # 5153491 opened April 16, 2026, still in use. 2. Review of BD BBL DrySlide Oxidase package insert showed "Use BD BBL DrySlide Oxidase from opened, resealed pouches within 1 week. Discard unused slides after 1 week". 3. Review of BD BBL DrySlide Indole package insert showed "Use BBL DrySlide Indole from opened, resealed pouches within 5 days. Discard unused slides after 5 days". 4. Review of bacteriology patient results showed the lab performs approximately 1,101 patient tests annually. 5. Interview with the TS #1 on May 12, 2026, at 9:30 AM confirmed the laboratory failed to ensure laboratory supplies were not used when they had exceeded their expiration date.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) (d) 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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493. 1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (d)(3) At least once each day patient specimens are assayed or examined perform the following for: This STANDARD is not met as evidenced by: Based on review of individualized quality control plan (IQCP) for the Siemens Stratus CS chemistry analyzer, December 2024 to date May 12, 2026 Stratus CS quality control (QC), patient results and interview with the technical supervisor (TS) #1, the laboratory failed to ensure that the IQCP for the Siemens Stratus CS chemistry analyzer was followed for 3 of 18 months. Findings: 1. Review of "Stratus CS IQCP" stated "Liquid controls are performed after each calibration, with each new shipment of previously calibrated or new TestPak lot, and monthly to verify the performance of the system". 2. Review of Siemens Stratus CS chemistry analyzer QC showed no QC was performed in December 2024 for the analytes troponin, creatinine kinase myocardial band (CKMB), pro-B-type natriuretic peptide (pBNP), and D-dimer and no QC was performed in April and May 2026 for the analyte troponin. 3. Review of Siemens Stratus CS chemistry analyzer patient results showed approximately 1,564 patient results annually. 4. Interview with the TS #1 on May 12, 2026 at 11:00 AM confirmed the laboratory failed to ensure Stratus CS IQCP was followed.

D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) (d)(10) Establish or verify the criteria for acceptability of all control materials. (d)(10)(i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (d)(10)(ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (d)(10)(iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. This STANDARD is not met as evidenced by: Based on review of the Siemens Dimension EXL 200 chemistry analyzer quality control (QC) records for 3 of 43 analytes, patient results, and interview with the technical supervisor (TS) #1, the laboratory failed to document how criteria was established for acceptability of control materials providing quantitative results for alkaline phosphatase (ALP) and free thyroxine (FT4). Findings: 1. Review of the Siemens Dimension EXL 200 chemistry analyzer QC records showed the laboratory used unassayed QC. The laboratory could not show how they established, documented, and defined statistical parameter criteria (mean and standard deviations) for acceptability of quantitative QC for the analytes: acetaminophen, albumin, ALP, alanine transaminase, aspartate transferase, ammonia, amylase, direct bilirubin, total bilirubin, calcium, chloride, high density lipoprotein, cholesterol, carbon dioxide, creatine phosphokinase, creatinine, c-reactive protein, D-dimer, digoxin, dilantin, ethanol, ferritin, glucose, glycohemoglobin, iron, lactic acid, low density lipoprotein, lactate dehydrogenase, lipase, magnesium, phosphorus, potassium, prostate specific antigen, sodium, total protein, triglyceride, blood urea nitrogen, uric acid, beta human chorionic gonadotropin, thyroid stimulating hormone, FT4, troponin I, and b-type natriuretic peptide. 2. Review of chemistry QC in the computer where testing personnel accept QC results showed the range for ALP level 3: 262.9-286.9. 3. Review of acceptable QC ranges established in the laboratory's QC log book showed ALP level 3: 270-294. The laboratory could not address the discrepancy in ALP ranges. 4. Review of Siemens Dimension EXL 200 chemistry analyzer patient results showed approximately 4,076 ALP patient results reported annually. 5. Review of chemistry QC in the computer where testing personnel accept QC results showed the range for FT4 level 3: 2.228-2.596. 6. Review of acceptable QC ranges established in the laboratory's QC log book showed FT4 level 3: 2.09-2.46. The laboratory could not address the discrepancy in FT4 ranges. 7. Review of Siemens Dimension EXL 200 chemistry analyzer patient results showed approximately 207 FT4 patient results reported annually. 8. Interview with the TS #1 on May 12, 2026 at 12:10 PM confirmed the laboratory failed to establish criteria for acceptability of control materials providing quantitative results.
D5471	CONTROL PROCEDURES CFR(s): 493.1256(e)(1)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(1) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or

	two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. This STANDARD is not met as evidenced by: Based on review of microbiology procedures, review of Becton Dickinson BBL DrySlide oxidase reagent quality control (QC), review of Becton Dickinson BBL DrySlide indole reagent QC, Becton Dickinson BBL P disk QC, Becton Dickinson BBL Taxo Discs for Differentiation of Group A Streptococci QC, patient results and interview with technical supervisor (TS) #1, the laboratory failed to ensure oxidase reagent, indole reagent, BBL P disc and BBL Taxo Discs for Differentiation of Group A Streptococci were tested for positive and negative reactivity. Findings: 1. Review of microbiology procedures showed no procedure for oxidase or indole. 2. Interview with TS #1 stated "we are supposed to perform oxidase and indole every day of patient testing". 3. Review of indole and oxidase 2026 QC showed patient testing was performed on 1/5, 1/22, 3/8, 5/5 and no QC was performed. 4. Review of microbiology patient results showed approximately 1,101 microbiology patient results reported annually. 5. Review of BBL P disc procedure states "Each time that a patient sample is set up with a P disc, the QC organisms must be set up also to ensure proper reactivity". 6. Review of BBL P disc patient testing showed no QC documentation each day of patient testing. 7. Review of BBL P disc patient results showed approximately 16 sputum culture reported annually. 8. Review of BBL Taxo Discs for Differentiation of Group A Streptococci procedure states "Positive and Negative QC organisms should be tested each time that a patient sample is tested". 9. Review of BBL Taxo Discs for Differentiation of Group A Streptococci showed no QC documentation each day of patient testing. 10. Review of BBL Taxo Disc for group A patient results showed approximately 113 throat cultures reported annually 11. Interview with the TS #1 on May 12, 2026 at 11:00 AM confirmed the laboratory failed to check oxidase reagent, indole reagent, BBL P disc and BBL Taxo Discs for Differentiation of Group A Streptococci reagent for positive and negative reactivity.
D6096	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(7) (e)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratorys established performance characteristics are identified, and This STANDARD is not met as evidenced by: Based on review of new immunohematology laboratory information system (LIS), review of immunohematology patient results, review of patient charts and interview with technical supervisor (TS) #1, the laboratory director failed to ensure that all immunohematology remedial actions are taken and documented whenever significant deviations from the laboratory's established performance characteristics are identified. Findings: 1. Review of EPIC and SafeTrace, the new immunohematology LIS, revealed the laboratory started using EPIC and SafeTrace in February 2025. 2. Review of immunohematology patients showed on February 6, 2025 patient A received uncrossmatched blood. 3. Review of "compatibility tag" printout states: "crossmatch interpretation: uncrossmatched" "Comments: Emergency Issue-Compatibility testing NOT performed"-off to the side an unidentified testing personnel wrote "completed after release unit compatible" on the bottom of the page testing personnel #1 wrote "tech's initials and given emergency release" 4. Review of patient A in EPIC and

	SafeTrace showed no documentation of emergency release unit given, it only has the crossmatch results of patient A. 5. Review of patient A electronic medical record showed no emergency release unit given on February 6, 2026. 6. Review of immunohematology patient results showed approximately 531 patient results annually. 7. Interview with the TS #1 on May 12, 2026 at 11:00 AM confirmed the laboratory director failed to ensure that all immunohematology remedial actions are taken and documented whenever significant deviations from the laboratory's established performance characteristics are identified.