Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	25D1087077	02/13/2024
Name of Provider or Supplier	**Street Address, City, State**	
River Medical Healthcare Llc	2119 Hwy 82 E, Greenville, MS	

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
D1000	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(c) Certificate of waiver tests. A laboratory may qualify for a certificate of waiver under section 353 of the PHS Act if it restricts the tests that it performs to one or more of the following tests or examinations (or additional tests added to this list as provided under paragraph (d) of this section) and no others: (1) Dipstick or Tablet Reagent Urinalysis (non-automated) for the following: (i) Bilirubin; (ii) Glucose; (iii) Hemoglobin; (iv) Ketone; (v) Leukocytes; (vi) Nitrite; (vii) pH; (viii) Protein; (ix) Specific gravity; and (x) Urobilinogen. (2) Fecal occult blood; (3) Ovulation tests-visual color comparison tests for human luteinizing hormone; (4) Urine pregnancy tests - visual color comparison tests; (5) Erythrocyte sedimentation rate-non-automated; (6) Hemoglobin-copper sulfate-non-automated; (7) Blood glucose by glucose monitoring devices cleared by the FDA specifically for home use; (8) Spun microhematocrit; and (9) Hemoglobin by single analyte instruments with self-contained or component features to perform specimen/reagent interaction, providing direct measurement and readout. This STANDARD is not met as evidenced by: Based on review of laboratory records (to include analyzer quality control (QC), maintenance, calibrations and patient reported results) and interviews with the laboratory director/technical consultant (LD/TC) and testing personnel (TP), the laboratory failed to obtain a certificate of registration before performing and reporting patient results for tests not categorized as waived. Findings Include: 1. Based on review of the Cell Dyn Ruby hematology analyzer QC, calibration and maintenance from installation on 8/15/23 through 2/13/2024, it was confirmed the first patient CBC (complete blood count) was reported on 8/30/2023. Approximately 1,600 CBC patient results have been reported since 8/30/2023. 2. Based on review of the Alinity CI Series chemistry analyzer QC, calibration and maintenance from installation on 6/27 /2023 through 2/13/2024, it was confirmed the first patient chemistry test results were reported on 7/24/2023. Approximately 12,000 chemistry patient results have been

	reported since 7/24/2023. 3. Based on the Centers for Medicare & Medicaid (CMS) database the laboratory initially had a certificate of waiver and submitted a CMS 116 application form to the CLIA program which was entered into the CMS database on November 8,2023. It was determined the laboratory operated out of the scope of their certificate performing moderate chemistry testing, for 4 of 7 months. 4. Based on the CMS data base and hematology records and patients CBC results, the laboratory operated out of the scope of their certificate performing moderate hematology testing, for 2 of 7 months. 5. In an interview with the LD/TC on 2/13/2024 at 5:00 p.m., the LD/TC were not aware the laboratory was reporting patient test results before the laboratory certificate was upgraded to a certificate of compliance.
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on review of the Centers of Medicare and Medicaid Services (CMS) database system for proficiency and interview with the laboratory director/technical consultant (LD/TC), the laboratory failed to enroll and participate in an HHS approved proficiency testing (PT) program for Hematology -CBC (Complete Blood Count), Chemistry (General Chemistry, Endocrinology and Immunology). Findings Include: 1. Based on review of the CMS Casper report for proficiency testing, the laboratory did not generate a report for any proficiency testing program for the year 2023 or 2024. 2. Based on review of laboratory documents there was no documentation on the day of survey for enrollment or participation in an HHS approved proficiency program for Hematology, General Chemistry, Endocrinology or Immunology for 2023. 3. The LD/TC confirmed on 2/13/2024 at 3:30 p.m. that the laboratory was not enrolled in proficiency testing for Hematology, General Chemistry, Endocrinology and Immunology testing for 1 of 1 proficiency events in 2023.
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 laboratory procedure manual and interview with the laboratory director,technical consultant (LD/TC), the laboratory did not have available on the day of survey, written approved procedures that included the following when applicable to the test procedure (1 of 3 procedure manuals): Findings include: A. There were no written approved procedures covering the following areas: 1. Requirements for patient preparation, storage, preservation, transportation, processing and referral; and criteria for specimen acceptability and rejection as described in 493.1242 (this subpart.) 2. Written procedures for specimen collection to include steps for venipuncture, fingerstick and capillary collection. 3. The laboratory's system for entering results in the patient record and reporting patient results. 4. Written procedure urine collection procedures for both male and female patients. 5. Written procedures to follow when the Cell Dyn Ruby hematology or Alinity CI Series chemistry analyzers become inoperable. 6. Written labeling policy for specimens to ensure positive identification. B. In an interview with the LD/TC on 2/12/2024 at 3:00 p.m., it was confirmed the laboratory procedure manual did not include the procedures mentioned above.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures and interview with the laboratory LD/TC, the laboratory director failed to ensure a comprehensive QA (quality assessment) program designed to monitor and evaluate the overall quality of the total testing process (general laboratory, preanalytic, analytic and post analytic systems) was established and maintained to assure the quality of the laboratory services provided. Findings include: A. The laboratory director had not ensured the laboratory had a written QA program available the day of survey for review, that included the practices or issues related to the following when applicable to the test procedure: 1. Patient confidentiality. 2. Specimen integrity. 3. Complaint investigations. 4. Communications. 5. Personnel competency (education, training, evaluation). 6. Proficiency testing or QA activities. 7. Specimen submission, handling, and referral. 8. Establishment and verification of method performance specifications. 9. Control procedures. 10. Review and documentation of the effectiveness of corrective actions taken to resolve problems. 11. Monitoring and evaluating the accuracy and completeness of the laboratory test reports. 12. Performance and

	periodic review of quality control, proficiency testing, and patient results. 13. Specifications of which qualified personnel will conduct QA reviews and how often these reviews will be conducted, systems and retention of QA records. 14. Revision of policies and procedures necessary to prevent recurrence of problems. 15. Discussion of laboratory QA reviews with appropriate testing personnel. 16. Documentation of QA activities. B. In an interview on 2/13/2024 at 5:00 p.m., the LD/TC confirmed the laboratory procedure manual did not include a Quality Assessment (QA) program established for the laboratory to follow and maintain.