Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D1096870	07/29/2025
Name of Provider or Supplier	**Street Address, City, State**	
River City Rehabilitation & Spine Specialists	2300 13th Street, Suite A, Columbus, GA	

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
D0000	A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on July 29, 2025. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(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 maintenance records review and staff interviews, the laboratory failed to perform and document ALL equipment maintenance checks as required by the instrument manufacturer from August 2023 and July 2025. Findings: 1. QA documents review revealed that Humidity checks were not recorded for the Diatron Pictus 500 Chemistry analyzer from August 2023 - July 2025. Per manufacturer, the Diatron Pictus 500 should operate at a relative humidity (RH) range of 35% - 85%. 2. An interview with the laboratory director at approximately 12:20 PM confirmed no documentation of relative humidity from August 2023 through July 2025.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1)

	(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on maitenance records review and staff interview, the laboratory failed to document corrective action plan for the Specialty Chemistry in the laboratory from January 2024 to December 2024. Findings: 1. Review of refrigerator logs storing chemistry reagents revealed refrigerator temperatures were out of range (9 degree celcius on 3/13/24, 3/14/24, 3/22/24, 3/29/24, 4/23/24, 5/14/24, 6/14/24 and 1 degree celcius on 7/30/24, 8/14/24, 8/19/24, 8/21/24, 9/4/24, 9/10/24, 10/14/24, 10/28/24, 11/4/24,11/25/24, 12/2/24, 12/16/24 and 12/30/24). There were no corrective actions documented, at the time of survey, by the testing the personnel and checked by the laboratory director. 4. Interview with the (TS) TP#3 (CMS 209) and laboratory director on 7/29/2025, at approximately 12:40 PM in the review room confirmed the aforementioned findings from January to December of 2024.
D6005	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(c) (c) The laboratory director must: (c)(1) Be onsite at least once every 6 months, with at least 4 months between the minimum two on-site visits. Laboratory directors may elect to be on-site more frequently and must continue to be accessible to the laboratory to provide telephone or electronic consultation as needed; and (c)(2) Provide documentation of these visits, including evidence of performing activities that are part of the laboratory director responsibilities. This STANDARD is not met as evidenced by: Based on maintenance records review and interview with the laboratory staff, the laboratory director failed to ensure that ALL pre analytic, analytic and post analytic Quality Assurance (QA) guidelines were followed to identify and fix problems in the laboratory from August 2023 - July 2025 as required by Clinical Laboratory Improvement Amendments (CLIA). Findings: 1. QA documents review revealed the lab director failed to identify that Humidity checks were not recorded for the Diatron Pictus 500 Chemistry analyzer from August 2023 - July 2025. Per instrument manufacturer, the Diatron Pictus 500 should operate at a relative humidity (RH) range of 35% - 85%. 2. An interview with the laboratory director in the review room on 07/29/2025, at approximately 12:15 PM confirmed the lab director failed to ensure proper oversight of the laboratory from August 2023 - July 2025.