Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	51D0235474	09/14/2022
Name of Provider or Supplier	**Street Address, City, State**	
Rainelle Medical Center	176 Medical Center Drive, Rainelle, WV	

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	An announced, on site, routine recertification survey was conducted at Rainelle Medical Center on September 14, 2022, by the West Virginia Office of Laboratory Services. The laboratory was assessed for compliance with the Federal Clinical Laboratory Improvement Amendment (CLIA) regulations under 42 CFR 493. Specific deficiencies are explained below.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(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: (1) Water quality. (2) Temperature. (3) Humidity. (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 a tour of the laboratory and interview, the laboratory failed to ensure the environmental room temperature was being monitored and documented from a NIST calibrated thermometer. Findings: 1. A tour of the laboratory, 9/14/22 at approximately 11:00 AM, revealed the environmental room temperature was being monitored and documented from a non-calibrated thermometer (SIN:18F11). 2. An interview with the laboratory manager, 9/14/22 at approximately 11:00 AM, confirmed the thermometer was not NIST calibrated.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the

	manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of quality control (QC) records, written policies and procedures (P&P), and interview the laboratory failed to ensure the results of QC met the criteria for acceptability before releasing patient test results on 5 of 28 testing days in July 2022. Findings: 1. Review of QC records for July 2022 identified the following analytes out of acceptable range (>2SD) with patient results released: 7/5/22 CO2, 7/7 /22 Sodium, 7/11/22 Sodium, 7/12/22 Creatinine, Chloride, CO2, and Cholesterol, 7 /15/22 Chloride. 2. Review of P&P identified the process to handle out of range QC: "Run 2 levels of control each day of testing. If levels are out of range no testing will be performed until the problem has been resolved". No documentation of the corrective action to resolve the out of range QC could be located. 2. An interview with the laboratory manager, 9/14/22 at approximately 10:30 AM, confirmed the findings.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on review of quality assessment (QA) records and interview the laboratory failed to monitor and evaluate the processes for identifying critical test results and turnaround times (TAT) of test results for reporting. Findings: 1. Review of the laboratory critical value logbook revealed documentation of critical values being relayed to providers. No method for identifying all critical patient results to determine if they were appropriately communicated and documented could be located. 2. Review of QA records for May 2021 thru date of survey identified no process to monitor and assess the TAT for reporting test results. 3. An interview with the laboratory manager, 9/14/22 at approximately 8:30 AM, confirmed the findings.