Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	18D2189923	07/11/2024
Name of Provider or Supplier	**Street Address, City, State**	
Frontier Medical Associates Of Paintsville	713 Broadway Street Suite 301, Paintsville, KY	

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 Recertification Survey was conducted on 07/11/2024. The facility was found not to be in compliance with the laboratory requirements of 42 CFR Part 493 with deficiencies cited.
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 review of the Form Centers for Medicare and Medicaid Services (CMS) - 116, the review of manufacturer's information addressing the laboratory's hematology quality control (QC) materials, document review, and confirmed in staff interview, the laboratory failed to monitor and document temperatures of the storage refrigerator each day of operation to ensure the quality control materials were maintained in accordance with manufacturer's specifications for 18 of 18 total months of temperature records reviewed (January 2023 through June 2024). Findings included: Review of the laboratory's Clinical Laboratory Improvement Amendments (CLIA) Application for Certification (Form CMS - 116), signed and dated by the Laboratory Director (LD) on 07/10/2024, revealed the laboratory's normal days of operation were Monday through Saturday. Review of the manufacturer's information for the laboratory's hematology analyzer, revised in July 2013, revealed that after opening, control materials should be maintained at "2-8 [degrees] C [Celsius]" (35.6 degrees Fahrenheit (F) to 46.4 degrees F). Review of monthly refrigerator temperature logs for

	the refrigerator identified as "RH157" for the timeframe of 01/01/2023 through 06/30 /2024 revealed, "Take immediate action if temperature is too low (below 36 [degrees] F) or too high (above 46 [degrees] F)!" The logs also included instructions to, "Record the min/max [minimum/maximum] temperatures daily at the opening of the clinic of the previous 24 hours." The logs revealed multiple days of operation with no recorded temperatures for each month reviewed. During an interview on 07/11/2024 at 11:00 AM, the Clinic Manager (CM) confirmed the refrigerator identified as "RH157" was the refrigerator used for storing hematology quality control materials. The CM confirmed temperatures had not been monitored or recorded as required.