Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	18D2210599	09/24/2024
Name of Provider or Supplier	**Street Address, City, State**	
Frontier Medical Associates Of Prestonsburg, Inc	400 University Drive Stes 211a And 101, Prestonsburg, 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 09/24/2024. The facility was found not to be in compliance with the laboratory requirements of 42 CFR Part 493 with deficiencies cited.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on document review and confirmed in staff interview, the facility failed to ensure the Laboratory Director (LD) or their designee signed an attestation statement for proficiency testing (PT) as required for 1 of 8 events reviewed. Findings included: Review of the "Attestation Statement" for the "2024 Hematology / Coagulation 2nd Event," electronically submitted 07/19/2024, revealed, "Signatures Required - For all PT results, an attestation statement must be signed by testing personnel and the laboratory director and retained for a minimum of 2 years." The Attestation Statement revealed the document was not signed or dated by the LD or their designee. In an interview on 09/24/2024 at 1:00 PM, Office Coordinator #1 indicated the lack of a signature was an oversight.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.

	This STANDARD is not met as evidenced by: Based on document review and confirmed in staff interview, the laboratory failed to review the results obtained from proficiency testing (PT) for 1 of 8 events reviewed. Findings included: Review of the "Performance Review and Corrective Action Documentation 2024 Hematology/Coagulation 1st Event," revealed "After reviewing the evaluation reports, print this form, complete the information below and retain this form, along with the evaluation reports, for your records." There was no signature on the document to indicate the Laboratory Director, or their designee reviewed the PT results as required. In an interview on 09/24/2024 at 1:00 PM on 09/24/2024, Office Coordinator #1 indicated the lack of a signature was an oversight.
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 facility policy review and confirmed in staff interview, the laboratory failed to establish panic or alert values for complete blood count (CBC) testing and failed to establish a policy and procedure for reporting the values to medical providers for 24 of 24 months of quality control (QC) data reviewed. Findings included: Review of the facility laboratory procedure manual revealed no documented evidence the facility developed a list of panic or alert CBC values or a procedure for the reporting of these values to medical providers. During an interview on 09/24/2024 at 1:45 PM, Office Coordinator #1 stated there was no policy for the reporting panic or alert values for a CBC. During an interview on 09/24/2024 t 2:35 PM, the Chief Operating Officer stated she could not identify a panic or alert value policy for a CBC.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the

	laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on facility policy review, document review, and confirmed in staff interview, the facility failed to monitor the performance of the complete blood count (CBC) quality controls (QC) for the Sysmex XP300 analyzer for 24 of 24 months of QC data reviewed. Findings included: Review of the facility policy titled, "j. Sysmex CBC Protocols 1. Quality Control," signed by the Medical Director on 07/09/2024, revealed "Quality Control (QC) in the clinical laboratory is a system designed to increase the probability that each result reported by the laboratory is valid and can be used with confidence by the practitioner to make a diagnostic or therapeutic decision." The policy revealed "Laboratory supervisors are responsible for reviewing QC results." Review of the facility QC reports revealed three levels of QC were run and reviewed daily; however, there was no review of QC values over time to identify shifts and trends. During a concurrent document review and interview on 09/24/2024 at 2:45 PM, the Chief Operating Officer reviewed QC data and could not produce any evidence QC values were reviewed for shifts and trends.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on document review and confirmed in staff interview, the laboratory failed to have a qualified technical consultant (TC). This deficient practice had the potential to affect all patients who received services at the facility. Findings included: Review of the "Clinical Laboratory Improvement Amendments (CLIA) Application for Certification" signed by the Laboratory Director (LD) and dated 09/18/2024, revealed the laboratory performed complete blood count (CBC) tests, a moderate complexity test. Review of the "Laboratory Personnel Report," signed by the LD and dated 09/24 /2024, revealed no employee held the position of TC. In an interview on 09/24/2024 at 1:15 PM, Office Coordinator (OC) #1 stated she believed the previous LD served in the TC capacity, but he was replaced by the current LD on 02/28/2023. OC #1 stated she was not aware of anyone who currently held the TC position. In an interview on 09 /24/2024 at 1:55 PM, the LD stated no one held the position of TC.