Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0267074	11/15/2023
Name of Provider or Supplier	**Street Address, City, State**	
Ed Fraser Memorial Hospital	159 N 3rd St, Macclenny, FL	

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 recertification survey was conducted at Ed Fraser Memorial Hospital 11 /14/23 - 11/15/23. Ed Fraser Memorial Hospital was found not in compliance with the 42 CFR Part 493, Requirements for Laboratories.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on record review and staff interview, the facility failed to follow manufacturers instructions for quality control testing of the AVOXimeter 4000 in 2022 and 2023. The findings include: The ITC AVOXimeter 4000 operator's manual states "Routine quality control testing should be part of a comprehensive quality assurance program. Quality control testing of the ITC AVOXimeter 4000 consists of the following operations: Daily optical quality control, Weekly testing of one level of liquid controls." 1. The record review of the document titled "AVOX Daily QC Log" showed optical quality control was not documented on the following days: March 6, 2022; April 23, 2022; May 15, 2022; May 28, 2022; June 4, 2022; July 10, 2022; April 8, 2023; and April 9 2023. 2. The weekly liquid control testing documentation showed no quality control was performed between the week of August 24, 2023 and September 12, 2023. The interview with Testing Person A on 11/15/23 at 10am confirmed the quality control documentation was missing.
D5545	HEMATOLOGY CFR(s): 493.1269(b)(d)

	(b) For all nonmanual coagulation test systems, the laboratory must include two levels of control material each 8 hours of operation and each time a reagent is changed. (d) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on record review and staff interview, the facility failed to ensure PT (prothrombin time) and APTT (activated partial thromboplastin time) quality control (QC) material was being performed every eight hours for three of three months reviewed (August 14, 2023 November 13, 2023). The findings include: 1. The record review on 11/14/23 of the quality control documentation for PT testing showed QC was not performed every 8 hours of operation for the following dates: August 14, 18, 19, 21, 26, 27 of 2023 September 2, 3, 4, 5, 9. 10, 11, 16, 17, 20, 23, 24, 25, 26 of 2023 October 1, 7, 8, 9, 14, 15, 16, 21, 22, 23, 25, 29, 30 of 2023 November 1, 4, 5, 6, 7, 10, 11, 12 of 2023 2. The record review on 11/14/23 of the quality control documentation for APTT testing showed QC was not performed every 8 hours of operation for the following dates: August 14, 18, 19, 21, 23, 26, 27, 30 of 2023 September 1, 2, 3, 4, 5, 9, 10, 11, 17, 18, 20, 23, 24, 25, 25 of 2023 The facility procedure titled "Coagulation Testing" effective 2/15/2023 states "QC analysis is performed for the purpose of quality control. QC will be performed as follows: PT /INR: every 8 hours APTT: every 8 hours" The 11/14/23 interview with Testing Person N at 12:23pm confirmed PT and APTT QC was not performed every 8 hours. It was determined that 5 patients were affected.