Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0968323	09/27/2023
Name of Provider or Supplier	**Street Address, City, State**	
Advanced Care Emergi Center & Occupational Health	2339 S Us Hwy 1, Fort Pierce, 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	A recertification survey was conducted on September 27, 2023. Advanced Care Emergi Center and Occupational Health Clinic Inc clinical laboratory was not in compliance with 42 CFR 493, requirements for clinical laboratories.
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manual, observation of patient specimens, and interview, the laboratory failed to ensure the positive identification of a patient's specimen at the time of collection for 1 of 1 patient specimen collected during the survey. Findings: Review of the procedure titled, Routine Venipuncture read, "Label each tube. Each tube the patient's full name as it appears on the reference lab requisition, date and time of collection, initials of phlebotomist." Observation on 09/27/2023 at 11:13 AM, of a patient's blood collection tubes (one purple top tube and three red top tubes) showed only the last name of the patient was written on the tubes of blood. On 09/27/2023 at 11:15 AM, Testing Personnel B acknowledged she did not write the patient's full name, date or collection time on the tubes.
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 patient's test reports, the procedure manual and interview, the laboratory failed to establish a written procedure for correcting the specimen collection time for three of three patients' (#1, #2, #3) test reports. Findings: Review of three patient's hematology test results showed the collection time on the reports was after the analysis time. Patient #1's hematology test report indicated the specimen was analyzed on 01/24/2022 at 9:32 AM, and collected on 01/24/2022 at 9:37 AM. Patient #2's hematology test report indicated the specimen was analyzed on 02/06/2023 at 11: 19 AM, and collected on 02/06/2023 at 11:27 AM. Patient #3's hematology test report indicated the specimen was analyzed on 06/08/2023 at 12:25 PM, and collected on 06 /08/2023 at 1:34 PM. Observation on 09/27/2023 at 11:05 AM, of a patient specimen run on the hematology analyzer showed the analyzer automatically added a collection time that was after the analysis time. Review of the procedure manual revealed there were no directions on how to change the collection time from the hematology analyzer to the correct collection time of the patient's specimen. On 09/27/2023 at 11: 12 AM, the Technical Consultant acknowledged the collection times on the test reports were incorrect and there were no directions in the procedure manual on how to change the collection time from the hematology analyzer to the correct collection time of the patient's specimen..
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on review of the Laboratory Personnel Report, personnel records, and interview, the laboratory failed to verify the educational qualifications (degrees) for 1 of 3 Testing Personnel, (A). (See D6065).
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by:

	Based on review of the Laboratory Personnel Report, personnel records, and interview, the laboratory failed to verify the educational qualifications (degrees) for 1 Testing Personnel (A) out of 3 Testing Personnel (A, B, C). Findings: Review of the Laboratory Personnel Report, signed by the Laboratory Director on 09/19/2023, showed there were three employees listed as moderate complexity testing personnel. Review of the laboratory personnel folders showed there was no documentation of the educational degree for Testing Personnel A available for review. On 09/27/2023 at 11: 30 AM, Technical Consultant stated Testing Personnel A could not find her degree.