Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0870225	01/14/2020
Name of Provider or Supplier	**Street Address, City, State**	
Jellico Medical Center, Inc	188 Hospital Lane, Jellico, TN	

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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: ========== Based on lack of Proficiency Testing (PT) enrollment order confirmation and upon interview with the Laboratory Supervisor, it was determined the laboratory failed to enroll in proficiency testing for regulated analytes for hematology, chemistry, immunohematology, and coagulation testing for 2020. The findings include: 1. There was no documentation of Proficiency Testing enrollment for regulated analytes for hematology, chemistry, immunohematology, and coagulation testing for 2020. 2. An interview with the Laboratory Supervisor at approximately 1:30 p.m. on January 14, 2020 confirmed the laboratory failed to enroll in Proficiency Testing for 2020. ==========
D3007	FACILITIES CFR(s): 493.1101(b) The laboratory must have appropriate and sufficient equipment, instruments, reagents, materials, and supplies for the type and volume of testing it performs.

	This STANDARD is not met as evidenced by: ========== Based on the Laboratory's test menu on 1/13/2020 and upon observation of reagents for CSF (Cerebrospinal fluid) analysis, body fluid cell counts, PSA (Prostate-specific antigen) screening, Free T4, and test kits for Influenza A/B and Mononucleosis Spot Test, the laboratory failed to have sufficient regents to perform these tests that were within the laboratory's stated test performance menu. The findings include: 1. Review of the Laboratory's test menu as stated on 1/13/2020 and observation of reagents for CSF analysis, body fluid cell counts, PSA screening, and Free T4, and test kits for Influenza A/B and Mononucleosis Spot Test, the laboratory failed to have sufficient reagents &/or test kits to perform the tests that were within the laboratory's stated test performance menu. 2. An interview at approximately 1:30 p.m. on January 14, 2020 with the Laboratory Supervisor confirmed the laboratory was unable to perform tests as stated due to lack of sufficient reagents &/or test kits. ==========
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: ========== Based on lack of documentation for Linearity/Calibration testing for Chemistry analytes performed on the Siemens Chemistry Analyzer and upon interview with the Laboratory Supervisor, it was determined the laboratory failed to perform linearity testing every 6 months for 2019 to ensure reportable range of testing for electrolytes (sodium, potassium, chloride, and bicarbonate). The findings include: 1. There was no documentation of Linearity /Calibration testing for electrolytes performed on the Chemistry Analyzer since June 2019. 2. An interview at approximately 1:30 p.m. on January 14, 2020 with the Laboratory Supervisor confirmed that Linearity/Calibration testing was not performed at 6 month intervals in 2019 for electrolytes. ==========