Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D2227462	05/22/2023
Name of Provider or Supplier	**Street Address, City, State**	
Jellico Regional Hospital, Llc	188 Hospital Ln, 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
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: Based on observation of the laboratory's reagent alcohol storage area and interview with the laboratory manager, the laboratory failed to ensure protection from flammable hazards in 2023. The findings include: 1. Observation of the laboratory's reagent alcohol storage area on May 22, 2023 at approximately 9:45 a.m. revealed three 4 Liter bottles of Fisher Chemical Methanol A456-4 and two 4 Liter bottles of Fisher Chemical 2-Propanol A461-4 stored on a wire shelf. 2. Interview with the laboratory manager on May 22, 2023 at approximately 9:45 a.m. confirmed the laboratory failed to ensure protection of flammable hazards for reagent alcohols, Methanol and 2-Propanol, in 2023.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of manufacturer complete blood count

	(CBC) quality control package insert and interview with the laboratory manager, the laboratory failed to label complete blood count quality control vials with open date and corrected expiration date on the date of the survey (05.22.2023). The findings include: 1. Observation of the laboratory on May 22, 2023 at 9:45 a.m. revealed the Sysmex XS-1000i CBC instrument (serial #63602) in use for patient testing. Observation of the Sysmex e-Check CBC control vials (lot #3074) in use revealed no labeling to indicate when they were opened or the corrected expiration date. 2. Review of the manufacturer quality control package insert revealed the following statement: "Open and recapped vials whose caps have been pierced will retain stability for 7 days if stored at 2-8 degrees C." 3. Interview with the laboratory manager on May 22, 2023, at 3:00 p.m. confirmed the laboratory had not labeled CBC quality control vials with open date and corrected expiration date on the date of the survey (05.22.2023). Word Key C = Celsius
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of validation records, and interview with laboratory supervisor, the laboratory director failed to approve validation studies for the Abbott i-STAT Chemistry analyzer prior to the start of patient testing on 02.24.2023. The findings include: 1. Observation of the laboratory on May 22, 2023 at approximately 10:00 a.m. revealed an Abbott i-STAT Chemistry analyzer (serial #429128) in use for patient testing. 2. Review of the validation studies for the Abbott i-STAT Chemistry analyzer revealed the validation studies had not been approved by the laboratory director at the time of survey. 3. Interview with the Laboratory Supervisor on May 22, 2023, at approximately 1:30 p.m. confirmed validation studies for the Abbott i-STAT Chemistry analyzer (serial # 429128) had not been approved by the laboratory director prior to patient testing that began February 24, 2023.