Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0892481	04/16/2024
Name of Provider or Supplier	**Street Address, City, State**	
Rural Health Services Consortium Of Upper East Tn	4307 Hwy 66 South, Rogersville, 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
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of the Beckman Coulter DxH 520 hematology analyzer operator's manual, laboratory policy, random review of patient test records (04/11/2024-04/12 /2024), and staff interview, the laboratory failed to follow its own policy to ensure the provider received patient results at the time of service when Complete Blood Counts (CBC) had histogram flagged results for four of ten patients. The findings include: 1. A review of the Beckman Coulter DxH 520 CBC hematology analyzer (serial # BG050284) operator's manual stated the following, "Risk of erroneous results. Flags, codes, and messages are evaluated when the sample is analyzed. Review the results and pay close attention to any flags, codes, or messages that are intended to alert you to issues with results or with the instrument... Some flagging occurs as a result of the flagging or editing of other parameters. In all cases, follow your laboratory's policy for reviewing results." 2. A review of the procedure titled "Abnormal WBC Differential Counts-Instrument Flags" revealed the following statement, "When the analyzer flags a result, the CBC will be rerun to verify the flag. Manufacturer instructions/suggestions will be followed for any remaining flags on the retested result. After exhausting the corrective actions of the manufacturer, a provider will review the results. This provider may then request that the test be referred our for further study." 3. A review of patient test records that included the hematology analyzer printout and the laboratory's electronic medical records (EMR) revealed the following: -Patient number: 109048, CBC performed on 04.11.2024. The instrument printout had a "PLT1:Debris" flag. The EMR report showed no flag. -Patient number:

	109978, CBC performed on 04.11.2024. The instrument printout had "Abnormal Diff, Cellular Interference, Suspect Diff" flag. The EMR report showed no flag. -Patient number: 105052, CBC performed on 04.11.2024. The instrument printout had "Abnormal Diff, Cellular Interference, Suspect Diff" flag. The EMR report showed no flag. -Patient number: 118260, CBC performed on 04.12.2024. The instrument printout had "Abnormal Diff, Cellular Interference, Suspect Diff" flag. The EMR report showed no flag. 4. During an interview with the laboratory lead on 04.16.2024 at 12:24 p.m., the surveyor asked the laboratory lead how the provider is notified of flagged CBC results if the flagged results are not transferred to the patient's EMR where the provider reviews patient test results; the laboratory lead responded, "The instrument printouts are given to the front office staff to be scanned into the patient's EMR after their visit." This confirmed the laboratory failed to follow its policy ensuring the provider received flagged results at the time of service when four of ten patient CBC results had histogram flags on the instrument printout but were not included on the EMR report. Word Key: WBC = White Blood Cell CBC = Complete Blood Count EMR = Electronic Medical Record PLT = Platelet Diff = differential
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on direct observation, review of the manufacturer's storage requirements, review of the laboratory's environmental records, and interview with the Technical Consultant, the laboratory failed to ensure proper temperature storage for blood collection tubes for six of six months reviewed in 2023 and 2024 when the room temperature range on the environmental log did not meet the manufacturer storage requirements. The findings include: 1. Observation of the laboratory revealed 16 packs, containing 100 tubes per pack, of Becton Dickinson (BD) dipotassium (K2) Ethylene Diamine Tatraacetic Acid (EDTA) blood collection tubes stored in the cabinet. 2. A review of the manufacturer's storage requirements revealed that the acceptable temperature range for tube storage is 4C (39.2F) to 25C (77F). 3. A review of six laboratory environmental records (January, April, August, and December 2023 and January and February 2024) revealed that the laboratory's acceptable room temperature range was 68F (20C) to 80F(26.667C), which does not meet the manufacturer's storage temperature requirements for BD K2 EDTA blood collection tubes. 4. Interview with the Technical Consultant on 04.16.2024 at 12:40 p.m. confirmed the acceptable room temperature range on the environmental log did not meet the manufacturer storage requirements for BD K2 EDTA blood collection tube storage. Word Key: C = degrees Celsius F = degrees Fahrenheit
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 the manufacturer control package insert, and interview with the laboratory lead, the laboratory failed to label three of three control vials used for performing quality control on the Complete Blood Count (CBC) hematology analyzer with an open date and a corrected expiration date on the date of the survey (04.16.2024). The findings include: 1. Observation of the laboratory on 04.16.2024, at 9:45 a.m., revealed the Beckman Coulter DxH 520 CBC analyzer (serial # BG050284) in use for patient testing. Also observed were three levels: abnormal low [lot 352415811], normal [lot 362415812], and abnormal high [lot 372415813]) of DxH 500 Series Control that were not labeled with an open date and corrected expiration date. 2. A review of the manufacturer control package insert revealed the following: "a maximum of 16 times within 16 days, provided they are handled properly". 3. An interview with the laboratory lead on 04.16.2024, at 9:49 a. m., confirmed that the laboratory failed to label CBC control vials with the open date and corrected expiration date for three of three control vials observed on the survey date (04.16.2024).
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Based on a review of final patient test reports and an interview with the Technical Consultant, the laboratory failed to ensure that the final patient test results for Complete Blood Count with automated white blood cell differential (CBC w/Diff) were accurately transcribed from the instrument printout to the electronic medical record (EMR) for one of ten patients reviewed. The findings include: 1. A review of CBC w/Diff results for patient 55698 performed on 04.11.2024 revealed the following: The results for Eosinophil (EO) absolute (#), Basophil (BA) #, Red Blood Cell (RBC), Hemoglobin (HgB), Hematocrit (HCT), Mean Corpuscular volume (MCV), Mean Corpuscular Hemoglobin (MCH), Mean Corpuscular Hemoglobin Concentration (MCHC), and Red Cell Distribution Width (RDW) were not reported correctly in the electronic medical record (EMR) as follows: Instrument Printout EMR EO# 0.61 0.610.01 BA# 0.01 5.10 RBC 5.10 14.97 HGB 14.97 43.6 HCT 43.6 85.5 MCV 85.5 29.4 MCH 29.4 34.3 MCHC 34.3 13.5 RDW 13.5 40.3 2. An interview with the Technical Consultant on 04.16.2024 at 12:24 p.m. confirmed that the laboratory failed to ensure that the CBC w/Diff results for patiet 55698 were accurately entered into the patient's EMR on 04.11.2024.