

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0311209	(X3) Date Survey Completed 06/18/2024
Name of Provider or Supplier Rural Health Services Consortium, Inc	Street Address, City, State 222 Oak St, Mountain City, 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
D5211	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory's Proficiency Testing (PT) records and staff interview, the laboratory failed to review performance evaluations for PT in 2023. The findings include: 1. A review of the laboratory's Wisconsin State Laboratory of Hygiene (WSLH) PT records revealed the performance evaluations for 2023 Events One, Two, and Three did not have documented reviews performed by the laboratory director. 2. An interview with the lead testing person on 06.18.2024 at 11:15 a.m. confirmed that the laboratory failed to document a review of the performance evaluations for PT Events One, Two, and Three in 2023.</p>
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the laboratory's policy, random review of patient test records from 05.20.2024, 05.21.2024, and 06.03.2024, and interview with the lead testing person, the laboratory failed to follow their Abnormal WBC Differential Counts Instrument Flag policy in May 2024. The findings include:</p>

1. Observation of the laboratory on 06.18.2024 at 9:30 a.m. revealed a Beckman Coulter DXH-520 (serial number BG060285) hematology analyzer used for CBC patient testing. 2. A review of the laboratory's Abnormal WBC Differential Counts Instrument Flags policy revealed, "When the analyzer flags a result, the CBC will be rerun to verify the flag." 3. A random review of patient test reports from the Beckman Coulter DXH-520 hematology analyzer from 05.20.2024, 05.21.2024, and 06.03.2024 revealed one of ten results with the following CBC flag: -Date 05.20.2024; Patient 86855; Flag PLT3: PLT/RBC Overlap: no documentation of sample rerun 4. An interview with the lead testing person on 06.18.2024 at 12:10 p.m. confirmed that the laboratory failed to follow the Abnormal WBC Differential Counts Instrument Flags policy when one of ten patients' CBC results was flagged with no documentation of a sample rerun on 05.20.2024. Word Key: Complete Blood Count = CBC White Blood Cell = WBC Platelet = PLT Red Blood Cell = RBC

D6053

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:
Based on observation of the laboratory, review of the Centers for Medicare and Medicaid Services (CMS) 209 form, testing personnel (TP) records, and staff interview, the technical consultant failed to perform interim competency during the first year of testing for one of one new testing personnel in 2023. The findings include: 1. Observation of the laboratory on 06.18.2024 at 9:30 a.m. revealed a Beckman Coulter DXH-520 (serial number BG060285) hematology analyzer used for Complete Blood Count (CBC) patient testing. 2. A review of form CMS-209 revealed one new testing personnel listed since the last survey, who perform moderately complex patient testing for CBC. 3. A review of testing personnel records revealed no documentation of interim competency for testing personnel number three (TP-3) during TP-3's first year of patient testing for CBC in 2023. 4. An interview with the technical consultant on 06.18.2024 at 11:10 a.m. confirmed the above survey findings.