Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2047726	05/16/2025
Name of Provider or Supplier	**Street Address, City, State**	
Riverside Tangier Medical Center	16186 Main Ridge Road, Tangier, VA	

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	An announced CLIA recertification survey was conducted at Riverside Tangier Medical Center on May 15, 2025 by the Virginia Department of Health's Office of Licensure and Certification. The inspection included an off-site exit interview with the laboratory director on 5/16/25. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. Specific deficiencies cited are as follows and includes one Condition under 42 CFR part 493 CLIA Regulation: D6000 -42 CFR. 493.1403 Laboratory Director.
D2014	TESTING OF PROFICIENCY TESTING SAMPLES (b)(6) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. This STANDARD is not met as evidenced by: Based on a review of the laboratory's proficiency testing (PT) records, lack of documentation, and interviews, the laboratory failed to retain attestation statements signed by the laboratory director (LD) for ten (10) of fourteen (14) PT module events reviewed on the date of the inspection, May 15, 2025. Findings include: 1. Review of the laboratory's American Proficiency Institute (API) PT documentation for fourteen event modules (2023 Event 3, 2024 Events 1-3, 2025 Event 1), revealed no signed LD attestation statements for: 2024 Chemistry Miscellaneous Event 1; 2024 Chemistry Miscellaneous Event 2; 2024 Chemistry Core Event 2; 2024 Chemistry Core Event 3; 2024 Hematology/Coagulation Event 1; 2024 Hematology/Coagulation Event 3; 2024 Microbiology Event 3; 2025 Chemistry Core Event 1; 2025 Hematology/Coagulation

	Event 1; 2025 Microbiology Event 1. 10 of 14 tested module events lacked LD signed attestation records as noted on 5/15/25. 2. The inspector requested the LD attestation records. No documentation was available for the PT events outlined above. The inspector inquired of the policy for PT attestations, the LD stated on 5/16/25 at 4 PM, "We are to retain all attestations and we will improve this process". 3. Interviews with the lead testing personnel on 5/15/25 at 1:30 PM and LD on 5/16/25 at 4:00 PM confirmed the above findings.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on a review of policies and procedures, hematology maintenance logs, monthly quality control (QC), proficiency testing (PT) records, Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), laboratory personnel files, lack of documentation, and interviews, the laboratory director (LD) failed to: 1. ensure that the established quality assessment (QA) policy for monthly review of hematology QC and Levey Jennings charts was followed for nine of twenty-four months reviewed (CROSS REFERENCE D6020 A); 2. ensure that the laboratory followed QA policy for retention of attestation statements for ten of fourteen PT module events reviewed (CROSS REFERENCE D6020 B); and 3. ensure that the laboratory followed their established policy to document hematology and chemistry six month competency assessments for one new testing personnel during the twenty-four months reviewed (CROSS REFERENCE D6053).
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur; This STANDARD is not met as evidenced by: A. Based on a review of policies and procedures, hematology maintenance logs, monthly quality control (QC) records, and interviews, the laboratory director (LD) failed to ensure that the established quality assessment (QA) policy for monthly review of hematology QC and Levey Jennings (LJ) charts was followed for nine (9) of twenty-four (24) months reviewed (survey timeframe: May 27, 2023 to May 15, 2025). Findings include: 1. Review of the laboratory's policies and procedures revealed a QA policy that included LD to review monthly quality checklists. 2. Review of the laboratory's hematology maintenance protocols revealed instructions to "review of QC, review of Levy Jennings, and review of patient results to be checked as completed monthly". 3. Review of the laboratory's Sysmex pocH instrument maintenance logs for the survey timeframe of 5/27/23 to 5/15/25 revealed no documentation that the QA review of QC, review of LJ, and review of patient results was completed for the following months: January 2024 July 2024 October 2024 November 2024 December 2024 January 2025 February 2025 March 2025 April 2025

	A total of 9 of 24 months lacked required QA monitoring for hematology QC and patient review. 4. The inspector requested to review documentation of the hematology QC review for the months outlined above. No records were provided. 5. Interviews with the lead testing personnel on 5/15/25 at 1:30 PM and LD on 5/16/25 at 4:00 PM confirmed the above findings. B. Based on a review of the laboratory's proficiency testing (PT) records, lack of documentation, and interviews, the Laboratory Director failed to ensure that the laboratory followed their Quality Assurance (QA) policy for retention of attestation statements for ten of fourteen PT module events reviewed on the date of the inspection, May 15, 2025. Cross Reference D2014.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) (b)(9) 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 a review of Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), laboratory personnel files, laboratory's policies and procedures, lack of documentation, and an interview, the technical consultant (TC) failed to follow established policy to perform/document semi annual hematology and chemistry competency assessments for one new testing personnel (TP) during the twenty-four months reviewed (survey timeframe: May 27, 2023 - May 15, 2025). Findings include: 1. Review of the CMS 209 personnel form revealed that the laboratory director (LD) also performs the duties of TC and identified two TP responsible for performing non-waived hematology Complete Blood Count (CBC) and iSTAT Chem8 during the review timeframe of May 27, 2023 to 5/15/25. 2. Review of the laboratory's personnel files revealed that TP A was hired and trained in June 2024 as a new TP. The inspector noted that the training was signed as completed /performed by the TC on 6/13/24. The inspector noted no other competency assessment records for TP A. (See Personnel Code Sheet.) 3. Review of the laboratory's policies and procedures revealed a protocol (titled: Competency Evaluation Program) that stated: "The competency evaluation program for Riverside Tangier Medical Center Laboratory has been designed to ensure that all staff members are trained and maintain their competency to perform all assigned tasks and is divided into three main areas: initial training, six month follow up competency, and annual review." The policy stated under heading Six Month Review, "Each employee will complete a six month competency review. Competency evaluations will be completed for each new employee. The checklist must be completed after six months of employment." 4. The inspector requested to review a semi annual competency Sysmex CBC and Abbott iSTAT chem8 assessments for TP A. No records were available for review. 5. Interviews with the lead testing personnel on 5/15/25 at 1:30 PM and LD on 5/16/25 at 4:00 PM confirmed the above findings.