Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2047726	06/09/2021
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 June 9, 2021 by the Virginia Department of Health's Office of Licensure and Certification. The inspector noted that the laboratory performs SARS-CoV-2 (COVID-19) testing and was in compliance with the applicable COVID-19 reporting requirements. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. Specific deficiencies cited are as follows:
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on a review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report Form (CMS 209), personnel records, proficiency testing (PT) documentation, and interviews, the laboratory failed to follow their PT policy to verify the accuracy of chemistry testing after receiving zero (0%) scores due to non participation for two (2) of three (3) events reviewed in calendar year 2020. **REPEAT DEFICIENCY Findings include: 1. Review of the CMS 209 form with the primary medical center provider on 6/9/21 at 11:40 AM revealed that three (3) testing personnel (TP A-C) performed non-waived hematology and patient microalbumin/creatinine chemistry testing during the twenty-four month review timeframe (June 2019 to June 2021). See Personnel Code Sheet. 2. Review of the laboratory's personnel records revealed the laboratory director (LD) utilized PT for competency assessment and verification of accuracy for chemistry urine microalbumin /creatinine. 3. Review of the laboratory's American Proficiency Institute (API) PT

	records revealed failure to verify the accuracy of microalbumin/creatinine chemistry testing in 2020 due to non participation responses for the following Miscellaneous Chemistry Modules: 2020 Event 1 0% scores for Microalbumin and Creatinine; 2020 Event 2 0% scores for Microalbumin and Creatinine, long term unsuccessful noted by API; The inspector reviewed the PT records and noted instrument results and LD written comment for the two urine chemistries as: "Did not submit on time". The inspector requested to review self grade or additional accuracy evaluation documentation. No additional documentation was available for review. During an interview with the LD at approximately 5:30 PM, the LD stated "Yes, our PT is for accuracy verification of the chemistry tests but we have had continued issues with submitting the results on time which resulted in API reporting to us that we failed to participate. 2020 was a really hard year. I am working with our new tech to improve how we conduct the proficiency testing submissions. I will go back and document a self grade with the peer results". 4. An interview with the primary medical center provider on 06/09/21 at 2:30 PM and LD at 5:30 PM, confirmed the above listed findings.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of the laboratory's hematology quality control (QC) records, interviews, and lack of documentation, the laboratory failed to perform an evaluation of statistical analysis to identify possible shifts and trends for Complete Blood Count (CBC) testing on the Sysmex pocHi-100i hematology instrument for nine (9) of the twelve (12) months reviewed in calendar year 2020. Findings include: 1. A review of the available records for the pocHi hematology instrument's Sysmex Eightcheck Tri Level QC materials (levels 1-3) revealed that the laboratory did not have documentation of performing statistical analysis for the parameters of CBC testing (white blood cell count WBC, red blood cell count RBC, Hemoglobin HGB, hematocrit HCT, Platelet PLT, Lymphoctye LYM%, Monocyte MXD%, Neutrophil NEUT%) in the following months of calendar year 2020: February, March, April, May, June, July, September, October, November. The inspector requested documentation. No documentation was available. The primary medical center provider on 06/09/21 at approximately 1:30 PM stated: "I would defer to our lab director for this issue. I am not sure why the Levey Jennings (LJ) charts are missing for those months." 2. During an interview with the LD at approximately 5:30 PM, the LD stated: "I do not have a QA corrective action for the missing LJ review. I do believe that a final L/J will contain all of the missing charts. If needed, I will complete

	a corrective action. Our new testing personnel has now taken over the position and is on top of sending the data for review." 3. An interview with the primary medical center provider on 06/09/21 at 2:30 PM and LD at 5:30 PM, confirmed the above listed findings.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on a review of the laboratory's proficiency testing (PT) records, available corrective action records, interviews, and lack of documentation, the laboratory director (LD) failed to ensure a corrective action plan was followed and remedial action documented for four (4) unsatisfactory results in three (3) events reviewed in calendar year 2020. Findings include: 1. Review of the laboratory's 2020 American Proficiency Institute (API) PT records, a total of 3 events, revealed no evidence of remedial action for the following four (4) unsatisfactory proficiency events and analytes: 2020 Event 1 0% scores for non participation responses Microalbumin and Urine Creatinine; 2020 Event 2 0% scores for non participation responses Microalbumin and Urine Creatinine, long term unsuccessful noted by API; 2020 Event 2 0% scores for Glucose WB (GLU-03, GLU-04 unacceptable results); 2020 Event 3 0% scores for Glucose WB (GLU-05, GLU-06 unacceptable results). The inspector noted instrument results and LD written comment for urine chemistry as: "Did not submit on time". The LD's written comment for the glucose results "wrong instrument selected". 2. Review of the available corrective action forms revealed no corrective/ remedial action or self grade documentation for the events listed above. 3. An interview with the primary medical center provider on 06/09/21 at 2:30 PM and LD at 5:30 PM, confirmed the above listed findings.