

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D2047726	(X3) Date Survey Completed 05/15/2019
Name of Provider or Supplier Riverside Tangier Medical Center	Street Address, City, State 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, 2019 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows:
D2127	<p>HEMATOLOGY CFR(s): 493.851(d)</p> <p>Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on a review of hematology proficiency testing (PT) documentation, and an interview, the laboratory failed to ensure complete blood count (CBC) PT testing results were returned to American Proficiency Institute (API) for one (1) of six (6) events reviewed from June 2017 to the date of the survey on May 15, 2018. Findings include: 1. Review of the laboratory's American Proficiency Institute (API) hematology PT documentation, a total of six (6) events, revealed that the laboratory failed to submit PT testing results and received a failure to participate score for the following CBC module: 2017 Hematology Event 3 - 0% scores for Cell Identification, Red Blood Cell, White Blood Cell, Platelet, Hemoglobin, and Hematocrit. 2. In an interview with the primary medical center provider at 1:30 PM, the above listed findings were confirmed.</p>
D5215	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2)</p> <p>The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance</p>

(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), proficiency testing (PT) documentation, and interviews, the laboratory failed to verify the accuracy of microalbumin/creatinine chemistry testing after receiving a zero (0%) score due to non participation for one (1) of two (2) events reviewed in 2018. Findings include: 1. Review of the CMS 209 form revealed that testing personnel A and B performed non-waived patient microalbumin /creatinine chemistry testing. (See Personnel Code Sheet) 2. Review of the laboratory's 2018 American Proficiency Institute (API) PT records revealed no verification of accuracy due to a non participation response for: 2018 Event 2 Miscellaneous Chemistry Module: 0% score for Microalbumin and Creatinine. The inspector requested to review accuracy evaluation documentation. No additional documentation was available for review. During an interview with the lab director (LD) at approximately 12:30 PM, the LD stated "Yes, we have had continued issues with submitting the results on time which resulted in API reporting to us that we failed to participate". 3. In an interview with the primary medical center provider at 1: 30 PM, the above listed findings were confirmed.

D5217

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
CFR(s): 493.1236(c)(1)

At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.

This STANDARD is not met as evidenced by:

Based on a review of microscopy test logs, proficiency testing (PT) records, and an interview, the laboratory failed to verify twice annual accuracy of Potassium Hydroxide Wet Preparation (KOH Wet Prep) testing in calendar year 2017. Findings include: 1. Review of microscopy patient test logs revealed that Testing Personnel C performed KOH Wet Prep microscopy examination in the laboratory. (See Testing Personnel Code Sheet) 2. Review of the laboratory's 2017 American Proficiency Institute (API) KOH Wet Prep PT records revealed: 2017 Event 1- 0% score; 2017 Event 3 - 0% score (failure to participate); resulting in unsuccessful performance for KOH Wet Prep PT in 2017. 3. In an interview with the primary medical center provider at 1:30 PM, the above listed findings were confirmed.