Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 49D2047726	**(X3) Date Survey Completed** 05/26/2023
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 25-26, 2023 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. Specific deficiencies cited are as follows and includes the Condition under 42 CFR part 493 CLIA Regulation: D5400 -42 CFR. 493.1250 Analytic Systems.
D2093	ROUTINE CHEMISTRY CFR(s): 493.841(d) 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. This STANDARD is not met as evidenced by: Based on a review of proficiency testing (PT) documentation, and an interview, the laboratory failed to ensure Core Chemistry Module PT test results for Creatine Kinase (CK), Glycated Hemoglobin, Myoglobin, Troponin, Sodium (Na), Potassium (K), Chloride (Cl), ionized Calcium (iCa), Carbon Dioxide (CO2), Glucose, Urea Nitrogen (BUN), and Creatinine (Creat) were returned to American Proficiency Institute (API) within the program's deadline for one (1) of two (2) events in calendar year 2023. Findings include: 1. Review of the laboratory's 2023 API Core Chemistry PT documentation (Events 1-2) revealed that the laboratory failed to submit and received failure to participate scores for the following modules/analytes: 2023 Chemistry- Core Event 1: five of five challenges received zero percent (0%) scores for CK, Glycated Hemoglobin, Myoglobin, Troponin, Na, K, Cl, iCa, CO2, Glucose, BUN, and Creat for challenge samples 1B01-1B05. 2. An interview with the lab director on 5/25/23 at approximately 2:15 PM confirmed the above listed findings.
D2127	HEMATOLOGY

	CFR(s): 493.851(d) 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. This STANDARD is not met as evidenced by: Based on a review of proficiency testing (PT) documentation, and an interview, the laboratory failed to ensure hematology Complete Blood Count (CBC) PT testing results were returned to American Proficiency Institute (API) within the program's deadline for one (1) of three (3) events in calendar year 2022. Findings include: 1. Review of the laboratory's 2022 API hematology PT documentation (Events 1-3) revealed that the laboratory failed to submit and received failure to participate scores for the following CBC module: API Hematology 2022-Event 3: Zero percent (0%) scores for five of five challenge samples for Cell Identification (Lymphocyte, Monocyte, Granulocyte), Red Blood Cell Count, White Blood Cell Count, Platelet Count, Hemoglobin, and Hematocrit. 2. An interview with the lab director on 5/25/23 at approximately 2:15 PM confirmed the above listed findings.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of the laboratory's Centers for Medicare and Medicaid Services CLIA Application Form (CMS 116), procedure manual, 2021 Centers for Medicare and Medicaid Services Statement of Deficiencies Plan of Correction (CMS-2567 POC), manufacturer's user guide/package inserts, daily temperature/environment logs, lack of documentation, patient test logs, tour, analyzer performance verification records, quality control (QC) records and interviews, the laboratory failed to: 1. ensure an Abbott iSTAT chemistry procedure was signed/approved by the laboratory director (LD) while utilizing the analyzer to report patient Sodium (Na), Potassium (K), Chloride (Cl), Carbon Dioxide (TCO2), Ionized Calcium (iCa), Glucose (Glu), Urea Nitrogen (BUN), and Creatinine (Creat) results from September 23, 2022 to the date of the inspection on 5/25/23. See D5401 A; 2. follow an established LD approved CMS-2567 corrective action procedure to ensure timely submission of PT results for one of three hematology events in calender year 2022 and and one of two chemistry events year to date in 2023. See D5401 B; 3. monitor daily relative humidity percent and room/refrigerator temperatures to ensure manufacturer's operating and storage requirements were followed for one (1) of 1 hematology analyzer and QC materials utilized for monitoring Complete Blood Cell patient testing for twelve of the twenty-three months reviewed (timeframe: June 2021 to the date of the inspection on 5/25 /23). See D5413; 4. record an evaluation/verification of accuracy, precision, reportable range, and normal ranges for Abbott iSTAT Chem 8 testing after a physical move/installation from a partner laboratory site to their laboratory in September 2022

	prior to reporting thirty-four (34) Chem 8 panel test results as of the date of the inspection on 5/25/23. See D5421; 5. document two levels of external QC monthly per their established protocol to monitor Na, K, Cl, iCa, CO2, Glucose, BUN, and Creat reagent while reporting 34 patient iSTAT Chem 8 panels during eight (8) of 8 months reviewed as of the date of the inspection on 5/25/23. See D5445.
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: A. Based on a review of the laboratory's Centers for Medicare and Medicaid Services CLIA Application Form (CMS 116), procedure manual, lack of documentation, patient test logs, and an interview, the laboratory failed to ensure an Abbott iSTAT chemistry procedure was signed/approved by the laboratory director (LD) while utilizing the analyzer to report patient Sodium (Na), Potassium (K), Chloride (Cl), Carbon Dioxide (TCO2), Ionized Calcium (iCa), Glucose (Glu), Urea Nitrogen (BUN), and Creatinine (Creat) results from September 23, 2022 to the date of the inspection on May 25, 2023. Findings include: 1. A review of the laboratory's CMS 116 form with the lead testing personnel on 5/25/23 at approximately 11:50 AM revealed new testing performance of non-waived chemistry Chem 8 panels (Na, K, Cl, TCO2, iCa, Glu, BUN, Creat) utilizing Abbott iSTAT chemistry analyzer (Serial Number 21430606). 2. Review of the procedure manual revealed no policy or procedure for the iSTAT Chem 8 testing outlined above. The inspector requested to review the iSTAT Chem 8 procedure. The primary testing personnel provided a folder with a printed Abbott iSTAT manufacturer's procedure. The inspector noted that an attached procedure review sheet was left blank for LD review/approval. 3. Review of the laboratory's procedures revealed a quality assurance policy that outlined "new test procedures will be reviewed and approved by the laboratory director". 4. Review of the laboratory information system patient iSTAT logs revealed thirty-four Chem 8 panels were analyzed/reported during the review timeframe of 9/23/22 to the date of the inspection, 5/25/23. 5. An interview with the lab director on 5/25/23 at approximately 2:15 PM confirmed the above listed findings. B. Based on review of procedures, 2020 Centers for Medicare and Medicaid Services Statement of Deficiencies Plan of Correction (CMS-2567), proficiency testing (PT) records, and an interview, the laboratory failed to follow an established laboratory director (LD) approved procedure to ensure timely submission of PT results for one of three events in calendar year 2022 and and one of two events year to date in 2023. (Cross Reference D2093, D2127.) Findings include: 1. Review of the laboratory's procedure manual revealed: Corrective Action CMS-2567 (LD signed/approved 6/22/21) which outlined a corrective action protocol to ensure timely reporting of PT results to American Proficiency Institute (API) that stated, "The laboratory director has added the testing personnel to the API proficiency notifications for delivery dates, status updates, result submissions, and due dates for all proficiency testing. If results cannot be sent by Internet they will be mailed or faxed to API by the due date. The lab director will oversee this plan." 2. Review of the laboratory's 2022 Hematology PT (Events 1-3) and 2023 Core Chemistry PT documentation (Events 1-2) revealed the laboratory failed to submit and received failure to participate scores for: API

	Hematology 2022 Event 3: five of five challenges received zero percent (0%) scores for Cell Identification (Lymphocyte, Monocyte, Granulocyte), Red Blood Cell Count, White Blood Cell Count, Platelet Count, Hemoglobin, and Hematocrit; API Chemistry Core 2023 Event 1: five of five challenges received zero percent (0%) scores for Creatine Kinase, Glycated Hemoglobin, Myoglobin, Troponin, Sodium, Potassium, Chloride, ionized Calcium, Carbon Dioxide, Glucose, Urea Nitrogen, and Creatinine for challenge samples 1B01-1B05. 3. The inspector inquired of the primary testing personnel to describe PT proficiency testing protocols for result submissions. The primary testing personnel stated on 5/24/23 at approximately 12:30 PM, "I have recently been trained to submit the results online now that we have reliable Internet. I think the events were sent to the lab director to submit but it was while the director was out of the office so the results never made it on time". 4. An interview with the lab director on 5/25/23 at approximately 2:15 PM confirmed the above listed findings.
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 a review of procedures, manufacturer's user guide/package inserts, daily temperature/environment logs, lack of documentation, and an interview, the laboratory failed to monitor daily relative humidity percent (%) and room/refrigerator temperatures to ensure manufacturer's operating and storage requirements were followed for the Sysmex PocHi hematology analyzer and quality control (QC) materials utilized for monitoring Complete Blood Count (CBC) patient testing for twelve (12) of twenty-three (23) months reviewed (timeframe: June 2021 to the date of the inspection on May 25, 2023). Findings include: 1. Review of the laboratory's procedures revealed Quality Assurance protocols that outlined daily monitoring of environmental conditions that included laboratory room temperature/ humidity and refrigerator/freezer temperatures. The protocol stated "The testing personnel opening the facility laboratory will document temperatures and humidity levels on log sheets. As a quality assurance measure, the director will review and sign off the log on a monthly basis." 2. Review of the manufacturer's guidelines revealed the following temperature requirements: Sysmex PocHi Analyzer: Humidity operating range 30-85%, operating temperature 15-30 degrees Celsius (C). Sysmex PocHi CBC QC package insert - "Stable through expiration date when stored 2-8 C, opened stability is eight consecutive days after open stored at 2-8 C". 3. Review of the available laboratory records for June 2021 to 5/25/23 revealed no record of laboratory room temperature/humidity or refrigerator temperature monitoring for the following months: 2021- September, October, November, December; 2022- January, February, March, April, May, June, July, and August; a total of 12 months lacked temperature log records. The inspector requested to review documentation of the monitoring to manufacturer's specifications for the months outlined above. No additional records were available for review. 4. An interview with the lab director on 5/25/23 at approximately 2:15 PM confirmed the above listed findings.

D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on a review of the laboratory's Centers for Medicare and Medicaid Services CLIA Application Form (CMS 116), tour, review of policies, analyzer performance verification records, lack of documentation, and an interview, the laboratory failed to record an evaluation/verification of accuracy, precision, reportable range, and normal ranges for Abbott iSTAT Chem 8 testing after a physical move/installation from a partner laboratory site to their laboratory in September 2022 prior to reporting thirty-four (34) Chem 8 panel test results as of the date of the inspection on May 25, 2023. Findings include: 1. A review of the laboratory's CMS 116 form with the lead testing personnel on 5/25/23 at approximately 11:50 AM revealed new testing performance of non-waived chemistry Chem 8 panels for Sodium (Na), Potassium (K), Chloride (Cl), ionized Calcium (iCa), Carbon Dioxide (CO2), Glucose (Glu), Urea Nitrogen (BUN), and Creatinine (Creat) tests utilizing Abbott iSTAT chemistry analyzer. 2. During a tour of the laboratory on 5/25/23 at approximately 12:00 PM, the inspector inquired of the installation of iSTAT (serial number 21430604) and the go live date. The primary testing personnel stated: "We got the iSTAT from another Riverside office last fall". The inspector reviewed the data log onboard the analyzer and noted that patient testing started on 9/23/22 for Chem 8 reagent cartridges reporting Na, K, Cl, TCO2, iCa, Glu, BUN, Creat test results. 3. The inspector requested to review the installation performance records for the iSTAT instrument's eight (8) iSTAT chemistry analytes outlined above. The primary testing personnel located a copy of a linearity reportable range study that was performed on 8/2/22 while the analyzer was located at another offsite location. The inspector inquired regarding if performance specifications had been evaluated after the analyzer was relocated on 9/23/22 and up to the date of the inspection, 5/25/23. No additional records of verification of accuracy, precision, reportable range, and normal ranges for Na, K, Cl, iCa, CO2, Glucose, BUN, or Creat were available for review for the analyzer after relocation to the laboratory. 4. Review of the patient test logs revealed that the lab had resulted 34 iSTAT Chem 8 reports from 9/23/22 to 5/25/23. 5. An interview with the lab director on 5/25/23 at approximately 2:15 PM confirmed the above listed findings.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (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 policies/procedures, manufacturer's guidelines, quality control (QC) records, patient test logs, lack of documentation, and interviews, the laboratory failed to document two (2) levels of external QC monthly per their established protocol to monitor Sodium (Na), Potassium (K), Chloride (Cl), ionized Calcium (iCa), Carbon Dioxide (CO2), Glucose, Urea Nitrogen (BUN), and Creatinine (Creat) analytes while reporting thirty-four (34) patient iSTAT Chem 8 panels during eight (8) of 8 months reviewed as of the date of the inspection on May 25, 2023. Findings include: 1. Review of the laboratory's QC policy revealed instructions that stated "The laboratory will follow manufacturer's recommendations when running control specimens. Any remedial action by the laboratory will be documented on the QA corrective action form and reviewed by the laboratory director." Additionally, (under Analytical External Controls heading) the procedure stated, "iSTAT testing sites will perform external quality control testing every 30 days on each iSTAT and for each cartridge type used." 2. Review of the Abbott iSTAT manufacturer's procedure guidelines revealed QC instructions that stated, "Monthly QC procedures for integrity testing- print electronic simulator results and for each lot of Chem 8 cartridges perform/analyze Control Levels 1 and 3". 3. Review of the laboratory's 2022 and year to date 2023 QC records revealed no external QC or electronic simulator documentation for the iSTAT Chem 8. The inspector inquired of a description of the QC protocols for the iSTAT. The primary testing personnel stated on 5/25/23 at approximately 1:45 PM, "I have never run QC on the iSTAT". 4. Review of the patient test logs revealed that the lab had resulted 34 iSTAT Chem 8 reports (Na, K, Cl, iCa, CO2, Glucose, BUN, Creat) from 9/23/22 to 5/25/23 while not running external QC or documenting electronic simulator results per the protocols outlined above. 5. A follow up interview with the lab director on 5/26/23 at approximately 5:00 PM confirmed the above listed findings.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policy and procedure manual, quality assessment (QA) records, lack of documentation, and interview, the laboratory director (LD) failed to ensure that the QA policies were maintained during a review timeframe of September 2021 through the date of the survey on May 25, 2023. Findings include: 1. Review of the laboratory's policy and procedure manual revealed the following QA protocols: Test procedure policy that outlined a QA protocol - "new test procedures will be reviewed and approved by the laboratory director"; Daily monitoring of environmental conditions protocols - that outlined daily monitoring of environmental conditions that included laboratory room temperature/ humidity and refrigerator/freezer temperatures. The protocol stated "The testing personnel opening

	the facility laboratory will document temperatures and humidity levels on log sheets. As a quality assurance measure the director will review and sign off the log on a monthly basis"; QC policy - that stated "The laboratory will follow manufacturer's recommendations when running control specimens. Any remedial action by the laboratory will be documented on the QA corrective action form and reviewed by the laboratory director." 2. Review of the laboratory's available QA documentation revealed: No documentation that the Abbott iSTAT chemistry procedure was signed /approved by the LD prior to utilizing the new system to report patient Sodium (Na), Potassium (K), Chloride (Cl), Carbon Dioxide (TCO2), Ionized Calcium (iCa), Glucose (Glu), Urea Nitrogen (BUN), and Creatinine (Creat) results from September 23, 2022 to the date of the inspection on 5/25/23 -Cross Reference D5401; No documentation of corrective action when the laboratory failed to record room temperature/humidity or refrigerator temperature monitoring for four months in calendar year 2021 (September, October, November, December) and eight months in calendar year 2022 (January, February, March, April, May, June, July, and August) - Cross Reference D5413; No documentation of QA corrective action forms for failures to assay two levels of external QC monthly to monitor the iSTAT chemistry analytes (Na, K, Cl, TCO2, iCa, Glu, BUN, Creat) while reporting thirty-four patient Chem 8 panels from 9/23/22 to 5/25/23 - Cross Reference D5445. 3. A follow up interview with the lab director on 5/26/23 at approximately 5:00 PM confirmed the above listed findings.