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| <b>Statement of Deficiencies</b>                                                                                           | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br><br>49D2171958          | <b>(X3) Date Survey Completed</b><br><br>08/31/2026 |
| <b>Name of Provider or Supplier</b><br><br>Sentara Rmh Advanced Imaging Center                                             | <b>Street Address, City, State</b><br><br>2509 Pleasant Run Drive, Harrisonburg, 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                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
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| D0000              | An announced CLIA recertification survey was conducted at Sentara RMH Advanced Imaging Center's laboratory on August 27, 2026 by the Virginia Department of Health's Office of Licensure and Certification. The recertification survey concluded with off-site follow up interviews on September 1, 2026. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiency cited is as follows:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| D5413              | <p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT</p> <p>CFR(s): 493.1252(b)</p> <p>(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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on a tour, review of procedures, temperature monitoring records, manufacturer's user guide, lack of documentation, and interviews, the point of care testing (POCT) laboratory failed to retain documentation of monitoring room temperatures per protocol for Creatinine reagent storage and iSTAT analyzer operation for 28 of 28 months reviewed (April 3, 2024 to the date of the inspection August 27, 2026). Findings include: 1. During a tour of the POCT laboratory testing area on 8/27/26 at 2:00 PM, the inspector noted one box of 24 Abbott iSTAT Creatinine reagent cartridges (Lot number A26107, expiration date 10/14/26) in use for patient testing. The inspector noted that the manufacturer's packaging stated room temperature storage requirement as 18-30 C. 2. Review of the laboratory's procedures revealed an iSTAT Individualized Quality Control Plan (IQCP) protocol that stated</p> |

under headings outlined: Environment: "Electronic monitoring of refrigerator and room temperature was implemented in 2017 and has been effective in documenting proper temperature storage of iSTAT cartridges." Biennial Authorization of the IQCP: "On going Quality Assessment Monitoring has documented potential failures and potential causes that could lead to errors in test results included are pre-analytical, analytical, and post analytical phases of testing. Quality assessments are documented on secure shared drive. The IQCP will be reviewed regularly to ensure that it remains an effective control for risks with the test system." The inspector noted the above protocol was signed/approved by the facility's Clinical Specialist, Point of Care Testing on 9/12/23.

3. The inspector selected five random months to review the POCT room temperature monitoring for their iSTAT patient testing (February 2025, March 2025, July 2025, March 2026, July 2026) and requested the logs. The temperature logs were not available for review. Technical Consultant (TC) #1 and TC #2 stated at 3 PM on 8/27/26, "In preparation of this inspection we reached out to the Manager of Facility Services requesting the temperature logs. We have been informed that the temperature monitoring system requires a firmware update in order to pull the records. We are unsure how many days that update will take. We do not have access to the temperature logs today." The inspector expanded the room temperature monitoring request for the review timeframe of 4/3/24-8/27/26. The temperature monitoring records were not available for review. The inspector inquired if the laboratory reviewed/retained temperature outlier reports for the 28 months of review. TC #1 and TC #2 stated at 3:30 PM, "No, we did not. We have not had access to pull the environmental reports." \* See Personnel Code Sheet 4.

Review of the Abbott iSTAT online user guide revealed instructions, "Store cartridges at room temperature for the timeframe indicated on the cartridge box. Mark the box or cartridge pouches with the room temperature expiration date. Do not expose the temperatures above 30 C. Do not return cartridges to the refrigerator after room temperature equilibrium. The iSTAT analyzer operating temperature range is 16-30 C."

5. A follow up interview with TC #1 at 9:30 AM on 9/1/26 revealed that the Manager of Facility Services provided the laboratory an updated message stating, "Trane completed the firmware update and we lost the historical data. They did not tell us that we would lose all of our data."

6. An exit interview with TC #2 at 12:30 PM on 9/1/26 confirmed the above findings.