| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 49D2114944 | 07/27/2026 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Quest Diagnostics - Roanoke Ambulatory Surgery | 1102 South Jefferson Street, Roanoke, 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 Quest Diagnostics-Roanoke Ambulatory Surgery Center on July 23, 2026 by the Virginia Department of Health's Office of Licensure and Certification. The survey concluded with an offsite follow up interview with the Point of Care Testing Supervisor on 7/27/26. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows: |
| **D2007** | TESTING OF PROFICIENCY TESTING SAMPLES<br>CFR(s): 493.801(b)(1)<br><br>(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review the Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), proficiency testing (PT) records, lack of documentation, and interviews, the laboratory failed to rotate chemistry, hematology, and blood gas PT challenge samples among testing personnel (TP) responsible for patient iSTAT assays during 26 of 26 months reviewed (survey timeframe: May 15, 2024 to July 23, 2026). Findings include: 1. Review of the CMS 209 laboratory personnel form revealed that the laboratory director (LD) identified four TP qualified /responsible for performing patient non-waived point of care hematology, general and blood gas chemistry tests by Abbott iSTAT analyzer during the review timeframe of 5 /15/24-7/23/26 and identified "Personnel A" as holding the positions of TP and Technical Consultant (TC). *See Personnel Code Sheet 2. Review of PT documentation (2024 Events 2-3, 2025 Events 1-3, 2026 Events 1,2), a total of seven events, revealed that the laboratory utilized the following two enrollments: American Proficiency Institute (API) Core Chemistry iSTAT Modules for the following hematology, general and blood gas chemistry analytes: Hematocrit, Hemoglobin, |

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| | Calcium ionized, Carbon Dioxide, Chloride, Creatinine, Glucose, Partial Pressure of Carbon Dioxide, pH, Partial Pressure of Oxygen, Potassium, and Blood Urea Nitrogen; College of American Pathologists (CAP) WP3 iSTAT Modules for the following analytes: Prothrombin Time, International Normalized Ratio. 3. Review of the API records revealed that Personnel A signed attestations/performed the following: API 2024 Core Chemistry Event 3; API 2025 Core Chemistry Event 1; API 2025 Core Chemistry Event 2; API 2025 Core Chemistry Event 3; API 2026 Core Chemistry Event 1; API 2026 Core Chemistry Event 2; Personnel A performed six of seven API Core Chemistry iSTAT PT module events reviewed. Review of the CAP records revealed that Personnel A signed attestations/performed the following: CAP 2024 WP3 Event 2; CAP 2025 WP3 Event 1; CAP 2025 WP3 Event 3; CAP 2026 WP3 Event 1; CAP 2026 WP3 Event 2; Personnel A performed five of seven CAP WP3 iSTAT PT module events reviewed. 4. The inspector inquired regarding the laboratory's protocol for assigning PT challenges to testing personnel. The Point of Care Testing (POCT) Supervisor stated on 7/23/26 at 12 noon, "Our procedure is for the samples to be rotated. We failed to ensure that procedure was followed." 5. An interview with the LD, Quality Assurance Specialist, and POCT Supervisor on 7/23 /26 at 12:30 PM and a follow up interview with the POCT Supervisor on 7/27/26 at 4 PM confirmed the above findings. |
| **D2014** | TESTING OF PROFICIENCY TESTING SAMPLES<br><br>(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.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of proficiency testing (PT) records, lack of documentation, and interviews, the laboratory failed to retain attestation and/or analyzer result records for three of seven hematology and one of seven core chemistry PT modules during the 26 months of review (survey timeframe: May 15, 2024 to July 23, 2026). Findings include: 1. Review of the laboratory's PT records (2024 Events 2-3, 2025 Events 1-3, 2026 Events 1,2) a total of seven events per speciality module, revealed that the laboratory utilized the following two enrollments: American Proficiency Institute (API) Core Chemistry iSTAT Modules for hematology, general and blood gas chemistry testing on Abbott iSTAT analyzer; College of American Pathologists (CAP) WP3 iSTAT Modules for hematology Prothrombin Time, International Normalized Ratio testing on Abbott iSTAT analyzer. 2. Review of the laboratory's available PT records for the modules outlined above revealed that the records lacked the following: API 2025 Core Chemistry Event 1 - lab director (LD) attestation; CAP 2024 WP3 Event 2 - iSTAT analyzer PT/INR results; CAP 2025 WP3 Event 1 - LD attestation and iSTAT analyzer PT/INR results; CAP 2026 WP3 Event 2 - LD attestation. The inspector requested to review the attestation and analyzer result documentation for events listed above. The documentation was not available for review. The Point of Care Testing Supervisor (POCT) stated on 7/23/26 at 12:00, "I would have to get those additional records from my office at the main hospital campus and I will send them to you at a later time." 3. An interview with the LD, Quality |

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| | Assurance Specialist, and POCT Supervisor on 7/23/26 at 12:30 PM and with the POCT Supervisor on 7/27/26 at 4 PM confirmed the above findings. |
| **D5209** | PERSONNEL COMPETENCY ASSESSMENT POLICIES<br>CFR(s): 493.1235<br><br>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), personnel files, procedures, lack of documentation, and interviews, the laboratory did not retain records following their policy for four of four technical consultant (TC) competency assessment evaluations during the review timeframe of May 15, 2024 through July 23, 2026. Findings include: 1. Review of the CMS 209 laboratory personnel form with the Point of Care Testing (POCT) Supervisor on 7/23/26 at 10 AM revealed that the laboratory director (LD) identified Personnel A and B as qualified/responsible for performing duties of Technical Consultant (TC) for patient non-waived point of care hematology, general and blood gas chemistry testing in the ambulatory surgery center during the review timeframe of 5/15/24-7/23/26 (*See Personnel Code Sheet). 2. Review of personnel files and proficiency testing records for the review timeframe outlined above revealed that the following four laboratory personnel performed/conducted competency assessments as TC and assigned/reviewed/evaluated proficiency testing as LD designees during the review timeframe: Personnel A, B, C, and D (*See Personnel Code Sheet). The inspector noted that Personnel C and D were not included on the submitted CMS 209 and inquired as to the omission. The POCT Supervisor stated on 7 /23/26 at 11:30 AM, "We have had staff changes and or retirements since the last inspection." 3. The inspector requested to review the laboratory procedure/protocol outlining documentation of the competency assessment of the TC. Review of policy (title: Policy for Performance Assessment of Delegated Duties) revealed that "The Laboratory Director evaluates performance of technical consultant on delegated duties on Document QDMOQ306 with both lab director and assessed to sign and date the assessment form". 4. The inspector requested to review qualifications and competency assessments for the duties of TC for each Personnel A, B, C, and D. The POCT Supervisor provided competency assessments for each of the four evaluating their positions as point of care testing personnel. Documentation of TC competency assessments were not available for review. 5. An interview with the LD, Quality Assurance Specialist, and POCT Supervisor on 7/23/26 at 12:30 PM and a follow up interview with the POCT Supervisor on 7/27/26 at 4 PM confirmed the above findings. |
| **D6005** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(c)<br><br>(c) The laboratory director must: (c)(1) Be onsite at least once every 6 months, with at least 4 months between the minimum two on-site visits. Laboratory directors may elect to be on-site more frequently and must continue to be accessible to the laboratory to provide telephone or electronic consultation as needed; and (c)(2) Provide documentation of these visits, including evidence of performing activities that are part of the laboratory director responsibilities. |

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| | This STANDARD is not met as evidenced by:<br>Based on a review of records, lack of documentation, and interviews, the laboratory director (LD) failed to provide documentation of onsite visits with evidence of performing oversight director duties during ten of ten months after September 12, 2025 up to the date of the recertification on July 23, 2026. Findings: 1. A review of quality assessment records revealed no documentation of LD onsite visits to conduct oversight responsibilities during the review timeframe of May 15, 2024 to date of inspection on July 23, 2026. The inspector requested to review documentation of LD onsite visits. The records were not available to review on the day of the inspection. The inspector inquired regarding the laboratory's protocol for documentation of LD oversight onsite visits such as sign in/sign out logs, meeting minutes, and/or notes of observations. The POCT Supervisor stated on 7/23/26 at 12 PM, "I do not have the records with me but should be able to get them from my office at the main hospital campus and will send them to you later today." 2. During a follow up interview with the POCT Supervisor on 7/27/26 at 3:30 PM, "Laboratory Physical and Environmental Checklists" were provided for review. The inspector noted the provided safety checklists were dated as performed onsite: 9/16/24, 4/10/25, and 9/12 /25. The inspector noted that the checklists pertained to physical/environmental safety checks at the surgery center testing site. The inspector also noted that the provided records did not include documentation for the 10 month timeframe after 9/12/25 up to 7/23/26. The inspector requested additional documentation of the LD's onsite oversight duties. The POCT Supervisor stated on 7/27/26 at 4 PM, "The only documentation I have is the Spring and Fall 2024/2025 Laboratory inspection walk-through". 3. An interview with the LD, Quality Assurance Specialist, and POCT Supervisor on 7/23/26 at 12:30 PM and with the POCT Supervisor on 7/27/26 at 4 PM confirmed the above findings. |