

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D2114944	(X3) Date Survey Completed 10/15/2020
Name of Provider or Supplier Quest Diagnostics - Roanoke Ambulatory Surgery	Street Address, City, State 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
D0000	An announced CLIA Recertification on-site survey was conducted at the Quest Diagnostics Roanoke Ambulatory Surgery Center on October 15, 2020 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. The surveyor began off-site record review of documentation on October 13, 2020 . Specific deficiencies cited are as follows:
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>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</p> <p>This STANDARD is not met as evidenced by: Based on the review of the Laboratory Personnel Report Form (CLIA) (CMS-209 form), proficiency testing (PT) records, policy and procedures (P&P) and interview with the technical consultant, the laboratory failed to rotate PT among the seven (7) personnel who performed Hematology and Chemistry patient testing according to the established policy for six (6) of the eleven (11) events reviewed. Record review included 2018, 2019 and up to the date of survey on October 15, 2020. Findings include: 1. Review of the CLIA CMS 209 for revealed 7 testing personnel (TP) that performed testing from October 1, 2018 up to the date of survey on October 15, 2020. 2. Review of the College of American Pathologists (CAP) PT records revealed that TP A performed 6 of the 11 events as follows: CAP AQI (Blood Gases) 2018 Event C, CAP AQI (Blood Gases) 2019 Event A and C, CAP WP3 (Hematology Prottime/INR) 2019 Event C, CAP WP3 (Hematology Prottime/INR) 2020 Event A and B. (See attached personnel code sheet.) 3. Review of the P&P "Proficiency Test Handling and Result Submission for Point of Care Site" (signed by the lab director on 9/26/16 and 10/8/19) revealed on page 5: "When multiple persons and/or instruments are routinely</p>

used for patient testing, PT materials must be rotated among testing personnel, shifts, and instruments." 4. An interview with the technical consultant at approximately 11:00 AM confirmed the findings.