

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D2062123	(X3) Date Survey Completed 05/07/2026
Name of Provider or Supplier Quest Diagnostics Llc	Street Address, City, State 851 Middle St, Fall River, MA	
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	A CLIA recertification survey was conducted for Quest Diagnostics Massachusetts LLC, Fall River on May 7, 2026, pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 found at 42 CFR 493. The laboratory was found to be in full compliance with applicable CLIA requirements.
D2003	<p>ENROLLMENT CFR(s): 493.801(a)(2)(ii)</p> <p>(2)(ii) For those tests performed by the laboratory that are not included in subpart I of this part, a laboratory must establish and maintain the accuracy of its testing procedures, in accordance with 493.1236(c)(1).</p> <p>This STANDARD is not met as evidenced by: Based on record review of 2024 and 2025 CAP Proficiency Testing (PT) Postvasectomy Sperm Count records and interview conducted on 05/07/2026 with the laboratory general supervisor (GS), laboratory failed verify the accuracy of post vasectomy sperm motility testing at least twice annually in 2024 and 2025. Findings include: 1. Record review of 2024 and 2025 Postvasectomy Sperm Count PT records revealed no documentation that the laboratory verified the accuracy of their post vasectomy sperm motility testing in 2024 and 2025. 2. Record review of the laboratory procedure, Post Vasectomy Spermatozoa (Uncentrifuged), signed by the laboratory director on 12/5/2025 revealed, "Note in the motility field on worksheet the absence or presence of motility." 3. Record review of a patient test report dated 03/18 /2026 revealed that Time of Motility and presence or absence of sperm motility was reported. 4. Interview with the GS on 05/07/2026 at 11:30 AM confirmed the findings above. 5. The laboratory reported performed 30 post vasectomy sperm analysis in 2025.</p>
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p>

(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.

This STANDARD is not met as evidenced by:

Based on surveyor review of proficiency testing (PT) 2024 and 2025 records, and interview with the laboratory general supervisor (GS) conducted on 05/07/2026, the laboratory failed to sign 3 of 8 attestation statements for 2024 and 2025 PT testing events. The findings include: 1. Record review of the laboratory's 2024 and 2025 College of American Pathologist (CAP) PT records revealed a lack of signed attestation statements for the following PT events: a. CAP 2025 SEM-B (Postvasectomy Sperm Count) - not signed by the laboratory director (LD) b. CAP 2025 CM-B (Urinalysis and Clinical Microscopy) - not signed by the LD and testing personnel (TP) c. CAP 2025 CM-B (Clinical Microscopy Miscellaneous) - not signed by the LD or TP. 2. Interview with the GS on 05/07/2026 at 12:43 PM, confirmed the findings above.