

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D1019897	(X3) Date Survey Completed 06/25/2026
Name of Provider or Supplier Framingham Heart Study/Boston University	Street Address, City, State 73 Mt Wayte Ave, Ste 2, Framingham, 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
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) (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. This STANDARD is not met as evidenced by: Based on record review and interviews with Technical Consultant #1 (TC1) and Technical Consultant #2 (TC2), the laboratory failed to ensure that proficiency testing (PT) samples in the chemistry and hematology specialties were tested only by testing personnel (TP) listed on the CMS Form 209. Findings Include: 1. Record review on 6/25/2026 of the laboratory's CMS Form 209 revealed 2 of 2 TP are currently performing patient testing. 2. Record review on 6/25/2026 of the 2025 and 2026 to date attestation sheets for the laboratory's College of American Pathologists Hematology/Auto Diff (FH2), General Chemistry/Therapeutic Drugs (C), and Hemoglobin A1c (GH5) PT surveys revealed the following: FH2 2025 - FH2 - B, Event 2 attestation sheet was signed as performed by TC1 who is not listed as a TP on the CMS Form 209. 2026 - FH2 - A, Event 1 attestation sheet was signed as performed by TC2 who is not listed as a TP on the CMS Form 209. C 2025 - CA - Event 1 and CB - Event 2 attestation sheets were signed as performed by TC2 who is not listed as a TP on the CMS Form 209. GH5 2025 - GH5B Event 2 attestation sheet was signed as performed by TC2 who is not listed as a TP on the CMS Form 209. 3. Staff interview with TC1 and TC2 on 6/25/2026 at 11:30 AM confirmed the above findings. TC1 stated, "I fill in when there isn't anyone else to perform patient testing." 4. The laboratory performs 10,584 chemistry and 5,880 hematology tests annually.