

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  22D2125498	<b>(X3) Date Survey Completed</b>  09/30/2025
<b>Name of Provider or Supplier</b>  Ccrm Boston	<b>Street Address, City, State</b>  300 Boylston St, Newton, MA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	An onsite validation survey was completed on September, 30, 2025 at CCRM Boston Laboratory by the Massachusetts State Agency. The laboratory was surveyed to determine compliance with CLIA Regulations under 42 CFR Part 493.
<b>D2012</b>	<p>TESTING OF PROFICIENCY TESTING SAMPLES</p> <p>(b)(4) Laboratories that perform tests on proficiency testing samples must not engage in any inter-laboratory communications pertaining to the results of proficiency testing sample(s) until after the date by which the laboratory must report proficiency testing results to the program for the testing event in which the samples were sent. Laboratories with multiple testing sites or separate locations must not participate in any communications or discussions across sites/locations concerning proficiency testing sample results until after the date by which the laboratory must report proficiency testing results to the program.</p> <p>This STANDARD is not met as evidenced by: Based on a review of PT records and an interview with the Laboratory Director (LD), the laboratory used Proficiency Testing (PT) samples for annual competency assessment prior to the PT program's results submission date deadline. The findings include: 1. Record review on 09/30/2025 of 2024 and 2025 PT Records revealed the following: a. CAP AMH-B 2024 - PT results submission date deadline 11/26/2024. Tested and reported to CAP by Testing Personnel (TP)4 on 11/06/2024 and retested by TP3 and TP1 on 11/20/2024. b. CAP C-A 2025- PT results submission date deadline 03/25/2025. Tested and reported to CAP by TP1 on 03/05/2025 and retested by TP2 and TP3 on 03/11/2025. c. CAP Y-B 2025- PT results submission deadline 09/02/2025. Tested and reported to CAP by TP3 on 08/14/2025 and retested by TP1 and TP2 on 08/20/2025. 2. Record review on 09/30/2025 of Proficiency Testing Policy 89803.327, effective 02/11/2025, Section II, revealed the following statement, "Other</p>

staff can only assess PT samples (as part of competency assessment) after the deadline for submission of data to the testing provider" 3. Interview with the LD on 09/30/2025 at 12:15 PM confirmed the findings above.