

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D1074150	(X3) Date Survey Completed 09/07/2023
Name of Provider or Supplier Emerson Hospital Center For Specialty Care	Street Address, City, State 54 Baker Avenue Extension, Concord, 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 the Emerson Hospital Center for Specialty Care laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493. Please refer to Conditions of Participation for Clinical Laboratories 42 CFR Part 493.
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 proficiency testing record review and interview, the laboratory failed to ensure that all testing personnel tested proficiency testing samples as evidenced by the following: a) A review of proficiency testing record attestation statements for calendar years 2021, 2022, and 2023 (six testing events) revealed that only one of the personnel performing moderate complexity testing was also the only person performing proficiency testing samples (documented signature on the attestation form). b) The technical consultant confirmed in an interview on interview on 9/7/23 at 9:05 AM that only one person had routinely been performing proficiency testing samples.</p>