

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D2061396	(X3) Date Survey Completed 11/09/2021
Name of Provider or Supplier Labcorp At St Vincent Cancer & Wellness	Street Address, City, State One Eaton Place Suite 301, Worcester, 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 LabCorp at Saint Vincent Wellness & Cancer Center laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493. .
D6123	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(iii)</p> <p>The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the technical supervisor failed to fulfill the responsibility of verifying that the competency of the staff was evaluated through review of quality control records as evidenced by the following: a) A review of hematology quality control records from 11/20/19 to 10/17/21 (approximately two years of quality control) was performed. The review revealed that the technical supervisor had not documented a review of quality control records. In addition, the laboratory director had designated a person not qualified under 493.1449 - Standard: Technical supervisor qualifications to review the quality control records. b) The laboratory director confirmed in an interview on 11/9/21 at 10:55 AM that quality control records were not being reviewed by the designated technical supervisor. c) The laboratory performs 57,288 hematology tests annually, .</p>