Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	22D2061396	09/25/2019
Name of Provider or Supplier	**Street Address, City, State**	
Labcorp At St Vincent Cancer & Wellness	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. .
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to accurately indicate the name and address of the laboratory on the test report as evidenced by the following: a) On 9/25/19 twelve (12) patient final reports were reviewed in for hematology testing performed between 9/10/18 and 8/13/19. The review revealed that the name of the laboratory where testing was performed was not accurately indicated for all twelve (12) reports reviewed (accession numbers - B44754396, B45253048, B46026657, B46098780, B46907891, B47051434, B47707470, B47926988, B48826286, B48973602, B49330136, and B49943596). In each case the report footer indicated the laboratory name as "LabCorp Worcester", whereas the laboratory is officially CLIA certified under "LabCorp at Saint Vincent Wellness and Cancer Center". b) Interview with the laboratory general supervisor on 9/25/19 at 10:35 a.m. confirmed that the name of the laboratory on the final reports did not match what the laboratory is CLIA certified under. .

D5821	TEST REPORT CFR(s): 493.1291(k) When errors in the reported patient test results are detected, the laboratory must do the following: (k)(1) Promptly notify the authorized person ordering the test and, if applicable, the individual using the test results of reporting errors. (k)(2) Issue corrected reports promptly to the authorized person ordering the test and, if applicable, the individual using the test results. (k)(3) Maintain duplicates of the original report, as well as the corrected report. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to: 1) promptly notify the authorized person ordering the test and, if applicable, the individual using the test results of reporting errors; and 2) issue corrected reports promptly to the authorized person ordering the test and, if applicable, the individual using the test results as evidenced by the following: a) On 9/25/19 twelve (12) patient final reports were reviewed in for hematology testing performed between 9/10/18 and 8/13/19. The review revealed that one (1) of the twelve (12) reports (accession number B48973602 reported out on 7/3/19) was a corrected report for the manual differential portion of the complete blood count (CBC) analysis. The error had been discovered during a quality assessment review of reports in August of 2019. b) Review of the laboratory's information system revealed that the erroneous result (under lymphocytes "25 bands" was corrected to read "25 atypical lymphs"). However, there was no indication that the report indicated it was a corrected report. Furthermore a telephone contact by the laboratory technologist on 9/25/19 at 10:49 AM to the physician practice receiving the results revealed that a revised CBC report was not available in the patient's medical record. c) The laboratory had policies and procedures titled "Clinical Corrected Reports" indicating that the laboratory, "Upon discovery of an incorrect result must issue a corrected report....The client is notified of the error and is given the corrected report." In this case these procedures were not followed. d) The laboratory performs 56,862 CBC tests annually.