

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0864898	(X3) Date Survey Completed 06/22/2021
Name of Provider or Supplier Comprehensive Cancer Center	Street Address, City, State 1180 N Indian Canyon Dr, Ste E-218, Palm Springs, CA	
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
D2130	<p>HEMATOLOGY CFR(s): 493.851(f)</p> <p>Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing (PT) result reports, the laboratory's records and interview with the laboratory testing personnel, it was determined that the laboratory failed to achieve satisfactory performance for the same analyte, WBC cell differentials, in two consecutive events was unsuccessful performance. The findings included: a. The laboratory used Sysmex XN 1000 analyzer to perform Complete Blood Cell Count (CBC) including WBC (white blood cell) with cell differential, RBC (red blood cell) hemoglobin (Hgb), Hematocrit (Hct) and Platelet count (Plt), and enrolled with CAP (College of American Pathologist) PT program. b. The laboratory reported WBC count with automated cell differential and verified with manual cell differentials when needed. c. The laboratory attained scores of 60% for WBC cell differential for both the Q3 2020 and Q1 2021 CAP hematology PT events which were unsatisfactory for two out of two, resulted an unsuccessful performance d. The laboratory affirmed (6/22/21 @ 12:35PM) that the laboratory attained scores of 60% for WBC Cell differential for the Q3 2020 and Q1 2021 CAP hematology PT events which were unsatisfactory for two out of two and resulted an unsuccessful performance. e. The laboratory performed CBC in approximately 240 patient samples monthly.</p>
D5411	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>Test systems must be selected by the laboratory. The testing must be performed</p>

following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.

This STANDARD is not met as evidenced by:

Based on touring and observing the laboratory facility, review the temperature records, observed the thermometers devices, and interview with the laboratory testing personnel, it was determined that the laboratory failed to follow the manufacturer's instructions and in a manner that provides proper temperature monitoring within the laboratory's stated performance specifications for each test/temperature system. The findings included: a. The laboratory used various refrigerators and freezers to store the reagents and supplies and to assure the quality and stability of the reagents to ensure the reliability and accuracy of the testing results. b. The laboratory used and/or mixed used various types of thermometer devices including the traditional analog thermometer in a liquid filled bottle, a digital Fisher Scientific, continuous temperature monitor system, and/or Wi-Fi monitor systems. c. Observed (6/22/21 @ 11:35 AM) a Fisher Scientific digital thermometer (Therm A) co-used in the Norlake scientific double door refrigerator equipped with a continuous temperature monitor system. d. This Therm A devices equipped with "Memory Clear", "Mode", and "Alarm On/Off". e. At the survey time (6/22/21) this device indicated 7 oC (current), 12 oC Lo, 30 oC Hi and Alarm On with a red dot. f. Interview with one testing personnel (TP) to provide the information of the Therma A had indicated. g. This TP did not provide acceptable information and indicated that the laboratory is currently using "Wi-Fi" systems to monitor the laboratory temperature conditions to a designated personnel/department. h. The designated person failed to show the working "Wi-Fi" temperature monitor systems. i. Further observed the Therm A device, pushed "Mode" and "Min" and "Max" appeared with "LL oC under Min, HH oC under Max.

D6000

MODERATE COMPLEXITY LABORATORY DIRECTOR
CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:

Based on review of the laboratory's proficiency testing (PT) result reports, the laboratory's records and interview with the laboratory testing personnel, it was determined that the laboratory failed to achieve satisfactory performance for the same analyte, WBC cell differentials, in two consecutive events was unsuccessful performance. The findings included: a. The laboratory used Sysmex XN 1000 analyzer to perform Complete Blood Cell Count and enrolled with CAP (College of American Pathologist) PT program. b. The laboratory reported WBC count with automated cell differential and/or manual cell differentials, when needed. c. The laboratory attained scores of 60% for WBC Cell differential for the Q3 2020 and Q1 2021 CAP hematology PT events which were unsatisfactory for two out of two, which constituted unsuccessful performance see D-2130.

D6016

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(4)(i)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:
Based on review of the laboratory's proficiency testing (PT) result reports, the laboratory's records and interview with the laboratory testing personnel, it was determined that the laboratory director failed to ensure that the proficiency testing samples were tested as required under CLIA regulations. The findings included: a. The laboratory used Sysmex XN 1000 analyzer to perform Complete Blood Cell Count and enrolled with CAP (College of American Pathologist) PT program. c. The laboratory attained scores of 60% for WBC Cell differential for the Q3 2020 and Q1 2021 CAP hematology PT events which were unsatisfactory for two out of two, which constituted unsuccessful performance, see D-2130.

D6023

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(6)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system;

This STANDARD is not met as evidenced by:
Based on touring and observing the laboratory facility, review the temperature records, observed the thermometers devices, and interview with the laboratory testing personnel, it was determined that the laboratory director failed to ensure the establishment and maintenance of acceptable levels of analytical performance for each test system. The findings included: a. The laboratory used various refrigerators and freezers to store the reagents and the patient samples and to assure the quality and stability of the reagents and the patient samples to ensure the reliability and accuracy of the testing results. b. The laboratory failed to familiarize and follow the manufacturer's instruction of the Fisher Scientific digital thermometer see D-5411.