

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D1055084	(X3) Date Survey Completed 04/03/2019
Name of Provider or Supplier Compassionate Cancer Care	Street Address, City, State 4500 Brockton Ave Ste 107, Riverside, 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
D2122	<p>HEMATOLOGY CFR(s): 493.851(b)</p> <p>Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing (PT) result reports, and interview with the technical consultant, it was determined that the laboratory failed to attain an overall testing event score of at least 80 % was unsatisfactory. The findings included: a. The laboratory performed complete blood cell count (CBC) using Abbott Celldyn Emerald analyzer for patient samples. b. The laboratory enrolled its PT with American Proficiency Institute (API) to ensure and evaluate the proficiency testing performance requirements. c. The laboratory attained an overall PT testing in the 2018 2nd event score of 0 % was unsatisfactory. d. The laboratory performed CBC testing in approximately 50 patient samples monthly. e. The technical consultant affirmed (4/3 /2019 @ 2:50 PM) that the laboratory attained an overall score of 0% for the second 2018 PT event was unsatisfactory performance.</p>
D5441	<p>CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g)</p> <p>(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system</p>

performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's quality control (QC) records, and interview with the laboratory consultant, it was determined that the laboratory failed to establish and follow written policies and procedures to detect immediate errors and monitor over time the accuracy and precision of test performance that may be influence by change in test system performance and environmental conditions, and variance in operator performance. The findings included: a. The laboratory uses Abbott Celldyn Emerald instrument to perform complete blood cell count (CBC). b. The laboratory uses three levels QC materials; namely Low (L), Normal(N) , & High(H), purchased from the manufacture. c. Review of the QC records between 8/3/2019 thru 8/9/2019 for QC level N, the operator repeated three (3) times to get an acceptable QC level N results. d. According to the laboratory's Quality Control Policy, "Criteria For Acceptability of Patient Runs", there were no clear policies in terms of how many repeats the operator can perform in order to reach acceptable run before testing patient samples. e. The technical consultant affirmed (04/03/2019) that there was no specific re-run policy established.

D5801

TEST REPORT

CFR(s): 493.1291(a)

The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations.

This STANDARD is not met as evidenced by:

Based on review of the laboratory 's patient test result reports, and interview with the technical consultant, and the laboratory operator, it was determined that the laboratory failed to have an electronic systems in place to ensure the test results and other patient-specific date were accurately and reliably sent from the point of data entry to final report destination. The findings included: a. The laboratory uses Abbott Celldyn Emerald analyzer to perform complete blood cell count (CBC). b. The laboratory scan the patient instrument print-out CBC test result copy into its EMR (Electronic Medical Record) systems. c. The patient test results report contains the following patient data, in addition to its CBC results. Name: Comments: Patient ID: Sample ID: Type: Standard d. Review of four patient final test result reports, where the "Patient ID:" was given in a patient's birthday or patient's medical record identification number. e. On the other patient final test result reports, where the "Sample ID" was also given in patient's birthday or patient's medical record identification number. f. The patient date of birth or its Medical Record ID were not consistently entered to the Abbott Emerald Celldyn analyzer and failed to ensure the accuracy of the patient data transfer to its EMR system.

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 proficiency testing (PT) result reports, and interview with the technical consultant, it was determined that the laboratory director failed to ensure that the proficiency testing samples are tested as required under Subpart H of this part. The findings included: See D-2122

D6022

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(5)

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)(5) Ensure that the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:

Based on review of the laboratory records, and interview with the technical consultant, it was determined that the laboratory director failed to ensure that the quality control and quality assessment programs were established and maintained to identify failures in quality as they occur. The findings included: See D-2122, D-5441 and D-5801

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 review of the laboratory quality control records, and interview with the technical consultant, 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: See D-5441