

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  05D2024860	<b>(X3) Date Survey Completed</b>  01/04/2018
<b>Name of Provider or Supplier</b>  Comprehensive Cancer Center, La Quinta	<b>Street Address, City, State</b>  47647 Caleo Bay Dr, Ste 260, La Quinta, CA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5407</b>	<p><b>PROCEDURE MANUAL</b> CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on observation, review of the laboratory's written policies and procedures, and interview with the laboratory staff, it was determined that the laboratory failed to ensure that written procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. The findings included: a. Review of the laboratory written policies and procedures (P&amp;P) , there were no current laboratory director's signature to indicated that the laboratory's P&amp;P were approved, signed, and dated before use. b. The laboratory staff affirmed (01/04/2018 @ 12:20 pm) that no current laboratory director's approval, signatures and dated were noted for written P&amp;P.</p>
<b>D5441</b>	<p><b>CONTROL PROCEDURES</b> 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 performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed.</p>

This STANDARD is not met as evidenced by:  
Based on review of the laboratory quality control records, and interview with the laboratory staff, it was determined that the laboratory failed to monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance, and failed to document all control procedures performed. the findings included: a. The laboratory performed routine chemistry and CBC (complete blood cell counts) and released patient test results reports. b. By interview and observation, no evidence of a qualified personnel's verification of daily quality control shown. c. The laboratory staff affirmed (1/04/2018 @ 11: 35 am) no signature daily but monthly.

**D6004**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(a)(b)

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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:  
Based on review of the laboratory records, and interview with the laboratory staff, it was determined that the laboratory director failed to be responsible for the overall operation, including, but is not limited to the following, reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. The findings include: See D-5407 and D-5441

**D6018**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(4)(iii)

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)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;

This STANDARD is not met as evidenced by:  
Based on review of the laboratory's proficiency testing results reports, and interview with the laboratory staff, it was determined that the laboratory failed to ensure that all proficiency testing reports received were reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. The findings included; a. The laboratory enrolled its proficiency testing (PT) to

ensure the accuracy of the testing performance annually with CAP (College of American Pathologists). b. No evidence indicated that the laboratory director had reviewed the PT result reports when receive each time with the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action.