

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  05D0710102	<b>(X3) Date Survey Completed</b>  07/07/2023
<b>Name of Provider or Supplier</b>  Catalina Island Medical Center	<b>Street Address, City, State</b>  100 Falls Canyon Rd, Avalon, 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>D2098</b>	<p>ENDOCRINOLOGY CFR(s): 493.843(a)</p> <p>Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's proficiency testing records, and interview with the laboratory technical consultant on July 6, 2023, at 2:45 pm, the laboratory failed to attain a score of at least 80 percent of acceptable responses for free thyroxine in 2021 3rd event and is unsatisfactory free thyroxine analyte performance for the testing event. The findings include: 1. The laboratory participated in the API proficiency testing program for the year 2021. The laboratory received a 60% score for the free thyroxine analyte in 2021 3rd event which resulted in an unsatisfactory analyte performance. Therefore, the accuracy of the patient test results reported by the laboratory during the proficiency testing event cannot be assured and might have harmed patients. 2. The laboratory technical consultant on July 6, 2023, at 2:45 pm, affirmed that the laboratory received a 60% score for the free thyroxine analyte in 2021 3rd event. 3. The laboratory's testing declaration form, signed by the laboratory director on 6/30/2023 stated that the laboratory performs approximately 1,350 tests in endocrinology, annually.</p>
<b>D2105</b>	<p>ENDOCRINOLOGY CFR(s): 493.843(e)</p> <p>(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be</p>

maintained by the laboratory for two years from the date of participation in the proficiency testing event.

This STANDARD is not met as evidenced by:

Based on Surveyor review of laboratory's proficiency testing records, and interview with the laboratory technical consultant on July 6, 2023, at 2:45 pm, the laboratory failed to take remedial action after receiving an unsatisfactory free thyroxine analyte performance in 2021 3rd event. The findings include: 1. The laboratory participated in the API proficiency testing (PT) program for the year 2021. The laboratory received a 60% score for the free thyroxine analyte in 2021 3rd event. However, the laboratory did not take any remedial action for the failure except re-running the PT sample. Therefore, the accuracy of the patient test results reported by the laboratory during the proficiency testing event cannot be assured and might have harmed patients. 2. The laboratory technical consultant on July 6, 2023, at 2:45 pm, affirmed that the laboratory did not take any remedial or corrective action for the analyte failure at the 3rd event in 2021. 3. The laboratory's testing declaration form, signed by the laboratory director on 6/30/2023 stated that the laboratory performs approximately 1,350 tests in endocrinology, annually.

**D5401**

**PROCEDURE MANUAL**  
CFR(s): 493.1251(a)

A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

This STANDARD is not met as evidenced by:

Based on Surveyor review of laboratory's policy and procedure, patient test results and interview with the laboratory technical consultant on July 7, 2023, at 10:30 am, the laboratory failed to have policy & procedure for the CBC test. The findings include: 1. The laboratory used Horiba Micro ES60 automated CBC instrument to perform CBC test with 3-part differential. The instrument gave STi, G2, L1 alarm messages with the CBC test results for one patient (# 202306101) out of 14 samples, reviewed. However, the laboratory did not have a policy & procedure for the CBC test, so the testing person did not know what action need to take to resolve the alarm messages and did not resolve the problem and reported the test results with high values of WBC, GRA and HGB. Therefore, the accuracy of the patients' test results rendered by the laboratory cannot be assured and might have harmed patient. 2. The laboratory technical consultant on July 7, 2023, at 10:30 am, affirmed that the laboratory did not have the policy & procedure for the CBC test. 3. The laboratory's testing declaration form, signed by the laboratory director on 6/30/2023, stated that the laboratory performs approximately 13,100 CBC tests, annually.

**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 reappropriates 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 Surveyor review of laboratory's policy & procedure, proficiency testing and patient test records, and interview with the laboratory technical consultant on July 7, 2023, at 11:30 am, the laboratory director failed to assure laboratory's compliance with the applicable regulations and thus had impaired the laboratory test quality and potentially harmed patients. The findings include: See D2098, D2105 and D5401.

**D6019**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(4)(iv)

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)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory.

This STANDARD is not met as evidenced by:

Based on Surveyor review of laboratory's proficiency testing records from API, and interview with the laboratory technical consultant on July 6, 2023, at 2:45 pm, the laboratory director failed to assure that the laboratory followed an approved corrective action plan when any proficiency testing result is found to be unsatisfactory. The findings include: See D2105.

**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 Surveyor review of laboratory's proficiency testing records, and interview with the laboratory technical consultant on July 6, 2023, at 2:45 pm, the laboratory director failed to ensure the maintenance of acceptable levels of analytical performance for the free thyroxine test. The findings include: See D2098.

**D6031**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(13)

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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process;

This STANDARD is not met as evidenced by:

Based on Surveyor review of laboratory's policy & procedure, patient test records and interview with the laboratory technical consultant on July 7, 2023, at 10:30 am, the laboratory director failed to ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. The findings include: See D5401.