

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0710102	(X3) Date Survey Completed 06/19/2018
Name of Provider or Supplier Catalina Island Medical Center	Street Address, City, State 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.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D2087	<p>ROUTINE CHEMISTRY CFR(s): 493.841(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 review third quarter (Q3-2016) of the American Association of Bioanalysts (AAB) proficiency testing records and interview with the testing personnel, it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses for PO2 blood gas analyte. The findings included: a. Q3-2016, AAB reported an unsatisfactory proficiency testing score of 0% for PO2 analyte. b. Based on the laboratory's testing declaration submitted for 2017-2018, the laboratory analyzed and reported 22 Blood gases tests which included PO2 analyte. c. The testing personnel affirmed (6/19/2018, 14:30) that the laboratory failed in the proficiency testing for the above analyte.</p>
D5447	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on review and the lack of quality control (QC) records, and interview with the testing personnel, it was determined that the laboratory failed to document and</p>

performs each quantitative procedure, include two control materials of different concentrations. The findings included: a. The laboratory uses iStat instrument (Abbott) for Lactate and blood gases analytes. The laboratory does not analyze and perform each quantitative procedure, include two control materials of different concentrations. b. Based on the laboratory annual testing declaration submitted for 2017-2018, the laboratory analyzed and reported 121 Lactate, and 22 Blood gases tests. c. The testing personnel affirmed (6/19/2018, 14:30) that the laboratory did not have documentation to show of each quantitative procedure, include two control materials of different concentrations.

D5449

CONTROL PROCEDURES
CFR(s): 493.1256(d)(3)(ii)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on review and the lack of quality control (QC) records, and interview with the testing personnel, it was determined that the laboratory failed to document and performs each qualitative procedure, include a negative and positive control material. The findings included: a. The laboratory analyzed and reported infectious Mononucleosis (Mono), Influenza A & B (Flu), and Serum Human gonadotrophin (HCG) tests. The laboratory has no documentation to show that daily quality control (QC) materials are performed and documented. b. Based on the laboratory annual testing declaration submitted for 2017-2018, the laboratory analyzed and reported 19 Mono, 206 Serum HCG, and 89 Flu tests. c. The testing personnel affirmed (6/19 /2018, 14:30) that the laboratory did not have documentation to show of each qualitative procedure, include a negative and positive control material.

D5891

POSTANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1299(a)

The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's Critical Values policy and procedure, random patient test result and interview with the testing personnel, it was determined that the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the post analytic systems. The findings included: a. The laboratory's Critical Values policy and procedure stated: "All laboratory tests have reference ranges associated with them. If values are determined to be critical, the ordering physician or the on-call physician must be notified STAT. If the ordering provider is a non-staff physician, the CLS on duty must call the Physician's office and verbally relay the critical result." b. For one (1) out of one (1) random patient test result reviewed with Complete Blood Count (CBC) ordered on 10/330/2016 with a high

White Blood Cell (WBC) count. The laboratory has not established, follow, monitor and other mechanism when indicated correct problem problems that are identified. c. The testing personnel affirmed (6/19/2018, 14:30) that the laboratory has not established, follow, monitor, assess when indicated, correct problems identified in the post analytic systems.

D6021

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 quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's proficiency testing records, quality control (QC) records, Critical Values policy and procedure, random patient test result and interview with the testing personnel, it was determined that the laboratory director failed to ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. See D2087, D5447, D5449, and D5891.