

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0956124	(X3) Date Survey Completed 05/25/2021
Name of Provider or Supplier California Heart And Vascular Clinic	Street Address, City, State 790 W Orange Ave Ste B, El Centro, 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
D5200	<p>GENERAL LABORATORY SYSTEMS CFR(s): 493.1230</p> <p>Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed.</p> <p>This CONDITION is not met as evidenced by: Based on interview with staff, review of quality control records, laboratory policies and procedures, and lack of documentation, the laboratory failed to monitor and evaluate the overall quality of the general laboratory system. The cumulative effect of these systemic problems resulted in the laboratory's inability to ensure the accuracy and reliability of patient test results. The findings included: a. Refer to D5209.</p>
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on review of patient and quality control records, laboratory policies and procedures, lack of documentation and an interview with the testing personnel, for 28 out of 28 patients records reviewed from January 2019 to May 2021, it was determined that the laboratory failed to follow personnel competency policies and</p>

procedures. The findings included: a. The laboratory performs hematology (white blood cell, red blood cell, hemoglobin, hematocrit, platelet, and automated cell differential counts) testing on the Boule Medronic M Series analyzer (serial number 17489) and chemistry (sodium, potassium, blood urea nitrogen and creatinine) testing on the Abbott i-STAT MN-300-G analyzer (serial number 357812). b. Review of patients testing records, QC records and lack of documentation indicated that the laboratory performed hematology and chemistry testing for 28 out of 28 patient records reviewed from January 11, 2019 to May 11, 2021. For the following records reviewed, there was no documentation to show that testing personnel competency assessment was performed to ensure the accuracy of the patients test results: 1) HEMATOLOGY RECORDS DATE TESTED PATIENT 5/11/21 SM 4/7/21 IZ 3/21 /21 GC 2/17/21 MR 1/29/21 FP 12/29/20 LR 10/1/20 NP 8/12/20 MG 6/12/20 CD 4 /28/20 CC 2/24/20 MA 12/27/19 GR 11/14/19 FF 10/11/19 TS 8/1/19 JT 6/10/19 GS 4 /25/19 JL 1/11/19 MR 2) CHEMISTRY RECORDS DATE TESTED PATIENT 5/5 /21 LR 4/7/21 SD 3/31/21 AC 2/24/21 ER 1/18/21 VH 11/18/20 JA 11/11/20 JP 10/28 /20 AA 5/5/20 AG 1/15/20 PF c. The laboratory testing person affirmed (5/25/21 at approximately 11:00 am) that the laboratory did not perform competency assessments on the testing personnel.

D5400

ANALYTIC SYSTEMS
CFR(s): 493.1250

Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.

This CONDITION is not met as evidenced by:
Based on interview with staff, review of quality control records, laboratory policies and procedures, and lack of documentation, the laboratory failed to monitor and evaluate the overall quality of the analytic system. The cumulative effect of these systemic problems resulted in the laboratory's inability to ensure the accuracy and reliability of patient test results. The findings included: a. Refer to D5447.

D5447

CONTROL PROCEDURES
CFR(s): 493.1256(d)(3)(i)(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 quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
1. Based on review of patient and quality control records, lack of documentation and an interview with the testing personnel, for 3 out of 18 patients records reviewed from January 2019 to May 2021, it was determined that the laboratory failed to include at least two samples of different concentrations of control materials for the complete blood count testing performed for each day patient specimens are assayed. The

findings included: a. The laboratory performs complete blood count (white blood cell, red blood cell, hemoglobin, hematocrit, platelet, and automated cell differential counts) testing on the Boule Medtronic M Series analyzer (serial number 17489). b. Review of patients testing records and QC records indicated that the laboratory performed complete blood count patient testing for 3 out of 18 patient records reviewed from January 11, 2019 to May 11, 2021. For the following records reviewed, there was no documentation to show that quality control was performed to ensure the accuracy of the patients test results: patient "CC" tested 4/28/20; patient "NP" tested 10/1/20, and patient "FP" tested on 1/29/21. c. The laboratory testing person affirmed (5/25/21 at approximately 11:00 am) that the laboratory did not perform CBC quality control with each day patient specimens are assayed. 2. Based on review of patient and quality control records, lack of documentation and an interview with the testing personnel, for 10 out of 10 patients records reviewed from January 2020 to May 2021, it was determined that the laboratory failed to include at least two samples of different concentrations of control materials for the chemistry testing performed for each day patient specimens are assayed. The findings included: a. The laboratory performs sodium, potassium, blood urea nitrogen and creatinine testing on the Abbott i-STAT MN-300-G analyzer (serial number 357812). b. Review of patients testing records and lack of quality control records indicated that the laboratory performed patient testing for 10 out of 10 patient records reviewed from January 15, 2020 to May 5, 2021. For the following records reviewed, there was no documentation to show that quality control was performed to ensure the accuracy of the patients test results: patient "PF" tested 1/5/20, patient "AG" tested 5/5/20, and patient "AA" tested on 10/28/20, patient "JP" tested 11/11/20, patient "JA" tested 11/18/20, patient "VH" tested 1/18/21, patient "ER" tested 2/24/21, patient "AC" tested 3/31/21, patient "SD" tested 4/7/21, and patient "LR" tested 5/5/21. c. The laboratory testing person affirmed (5/25/21 at approximately 11:00 am) that the laboratory did not perform quality control with each day patient specimens are assayed.

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 interview with staff, review of quality control records, laboratory policies and procedures, and lack of documentation, the laboratory director failed to provide overall management and fulfill the laboratory director responsibilities. The cumulative effect of these systemic problems resulted in the laboratory's inability to ensure the accuracy and reliability of patient test results. The findings included: a. Refer to D6020. b. Refer to D6030.

D6020

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 program is established and

	<p>maintained to assure the quality of laboratory services provided.</p> <p>This STANDARD is not met as evidenced by: Based on interview with staff, review of quality control records, laboratory policies and procedures, and lack of documentation, the laboratory director failed to ensure that quality control programs are maintained to assure the quality of laboratory services provided. The findings included: a. Refer to D5447. b. Refer to D6049.</p>
<p>D6030</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12)</p> <p>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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;</p> <p>This STANDARD is not met as evidenced by: Based on interview with staff, review of quality control records, laboratory policies and procedures, and lack of documentation, the laboratory director failed to assure the testing personnel are competent and maintain their competency to perform test procedures and report patient test results promptly and proficiently. The findings included: a. Refer to D5209. b. Refer to D6046.</p>
<p>D6033</p>	<p>TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409</p> <p>The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on interview with staff, review of quality control records, laboratory policies and procedures, and lack of documentation, the technical consultant failed to provide technical oversight and fulfill the technical consultant's responsibilities. The cumulative effect of these systemic problems resulted in the laboratory's inability to ensure the accuracy and reliability of patient test results. The findings included: a. Refer to D6046. b. Refer to D6049.</p>
<p>D6046</p>	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)</p> <p>(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.</p>

This STANDARD is not met as evidenced by:
 Based on review of patient and quality control records, laboratory policies and procedures, lack of documentation and an interview with the testing personnel, for 28 out of 28 patients records reviewed from January 2019 to May 2021, it was determined that the technical consultant failed to assess and document the competency of the testing personnel. The findings included: a. The laboratory performs hematology (white blood cell, red blood cell, hemoglobin, hematocrit, platelet, and automated cell differential counts) testing on the Boule Medronic M Series analyzer (serial number 17489) and chemistry (sodium, potassium, blood urea nitrogen and creatinine) testing on the Abbott i-STAT MN-300-G analyzer (serial number 357812). b. Review of patients testing records, QC records and lack of documentation indicated that the laboratory performed hematology and chemistry testing for 28 out of 28 patient records reviewed from January 11, 2019 to May 11, 2021. For the records reviewed, there was no documentation to show that technical consultant evaluated the competency of testing personnel to assure that staff maintain competency to perform test procedures and report test results promptly, accurately, and proficiently. c. The laboratory testing person affirmed (5/25/21 at approximately 11:00 am) that the technical consultant did not perform competency assessment on the testing personnel.

D6049

TECHNICAL CONSULTANT RESPONSIBILITIES
 CFR(s): 493.1413(b)(8)(iii)

The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.

This STANDARD is not met as evidenced by:
 Based on review of patient and quality control records, laboratory policies and procedures, lack of documentation and an interview with the testing personnel, for 28 out of 28 patients records reviewed from January 2019 to May 2021, it was determined that the technical consultant failed to review quality control records. The findings included: a. Refer to D5447.