

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 12D2181735	(X3) Date Survey Completed 02/14/2022
Name of Provider or Supplier Pacific Vascular Institute	Street Address, City, State 99-115 Aiea Heights Drive Suite 276, Aiea, HI	
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
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory procedure manual and an interview with the General Supervisor on 02/14/2022 at 12:00 p.m., it was determined that the laboratory failed to provide a written procedure manual that described tests, assays and examinations that laboratory personnel could follow. The findings include: 1. The General Supervisor confirmed on 02/14/2022 at 12:00 p.m. that the Quality Control Plan in the laboratory procedure manual was provided by the iStat manufacturer and was not approved by the Laboratory Director. 2. The laboratory Quality Control Plan contained a section "Authorization of the IQCP". The General Supervisor confirmed on 02/14/2022 at 12:05 p.m. that testing personnel performed daily iStat quality control with Level I and Level III controls and that they were unaware of the implementation of an IStat IQCP Plan. 3. Section 2d of the laboratory Quality Control Plan describes the iStat blood gas and lactate test systems. The General Supervisor confirmed on 02/14/2022 at 12:10 p.m. that testing personnel do not perform blood gas or lactate testing. 4. Testing personnel documented patient iStat hemoglobin and hematocrit test results on the Laboratory Patient Test Log. The General Supervisor confirmed on 02/14/2022 at 12:15 p.m. that the laboratory did not report these results and that a procedure describing what to do with critical or abnormal hemoglobin and hematocrit values was not available for laboratory personnel to follow.</p>
D5421	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p>

Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

Based on a review of laboratory iStat records and an interview with the General Supervisor on 02/14/2022 at 12:45 p.m., it was determined that the laboratory failed to verify the performance specifications of the Abbott iStat test system, SN21410420 it introduced prior to reporting patient Chem 8+ test results. The findings include: 1. An Abbott representative performed an iStat System Verification between June 9-10, 2020. The iStat ACT Performance Verification Report summary statement was not reviewed, evaluated or approved by the Laboratory Director for iStat performance specifications to include accuracy, precision, reportable range, verification of manufacturer critical values as appropriate for the laboratory patient population. 2. The laboratory performs an estimated 300 iStat Chem 8+ tests annually.

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT

CFR(s): 493.1289(a)(c)

(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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

Based on a review of laboratory procedure manuals, quality control and iStat maintenance records and confirmation by the General Supervisor on 02/14/2022 at 11:00 a.m., it was determined that the laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems. The findings include: 1. The General Supervisor confirmed the laboratory did not have a written policy or procedures that describes how the following analytic systems are assessed: a. Test procedures b. Specimen and reagent storage conditions c. Equipment maintenance, calibration and function checks d. Quality control results e. Corrective actions f. Test records 2. The laboratory performs an estimated 300 iStat Chem 8+ tests annually.

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 an interview with the General Supervisor on 02/14/2022 at 12:50 p.m., it was determined that the laboratory failed to ensure that patient iStat Chem 8+ test results and other patient specific data are accurately and reliably sent from the point of entry to final report destination in a timely manner. The findings include: 1. The General Supervisor confirmed on 02/14/2022 at 12:55 p.m. that data electronically transmitted from the iStat hand held instrument to the patient medical record interface is not periodically verified for accuracy and timely reporting. 2. Laboratory Director review, evaluation and approval of this reporting system was not available for review during the 02/14/2022 survey.

D6013

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(3)(ii)

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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method;

This STANDARD is not met as evidenced by:

Based on a review of laboratory records and confirmation by the General Supervisor on 02/14/2022 at 12:45 p.m., it was determined that the Laboratory Director failed to ensure that the verification procedures performed by an Abbott iStat representative were reviewed, evaluated and approved as being adequate to determine the accuracy, precision and other pertinent performance characteristics of the method. The findings include: 1. The iStat ACT Performance Verification Report summary statement was not reviewed, evaluated and approved by the Laboratory Director. See CFR 493.1253, D tag D5421.

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 maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on a review of laboratory quality control records and an interview with the General Supervisor on 02/14/2022 at 12:00 p.m., it was determined that the Laboratory Director failed to ensure that a quality control program was established and maintained to assure the quality of laboratory services provided. The findings include: 1. The General Supervisor confirmed on 02/14/2022 at 12:00 p.m. that the

Quality Control Plan in the laboratory procedure manual was provided by the iStat manufacturer and was not approved by the Laboratory Director. See CFR 493.1251, D tag D5401.

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 a review of the laboratory procedure manual and confirmation by the General Supervisor on 02/14/2022 at 12:00 p.m., it was determined that the Laboratory Director failed to ensure that an approved procedure manual is available to all testing personnel responsible for any aspect of the iStat Chem 8+ testing process. The findings include: 1. The General Supervisor confirmed on 02/14/2022 at 12:00 p. m. that the Quality Control Plan in the laboratory procedure manual was provided by the iStat manufacturer and was not approved by the Laboratory director. See CFR 493.1251, D tag D5401.

D6032

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(14)

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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:

Based on a review of laboratory records and confirmation by the General Supervisor on 02/14/2021 at 1:00 p.m., it was determined that the Laboratory Director failed to specify in writing, the responsibilities and duties of the Clinical Consultant, General Supervisor and 11 testing personnel engaged in the performance of the preanalytic, analytic, and post analytic phases of iStat Chem 8+ testing, to include which procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results.