

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0710557	(X3) Date Survey Completed 10/24/2018
Name of Provider or Supplier Orchard Hospital Cardiopulmonary	Street Address, City, State 240 Spruce St, Gridley, 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
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory patient test result reports, lack of evaluation of proficiency testing (PT) performance documents, and interview with the testing personnel (TP), it was determined that the laboratory failed to verify at least twice annually, the accuracy of any test or procedure it performed and reported that is not included in subpart I of 42 CFR part 493. The findings included: a. The laboratory performed ABG (arterial blood gases) and report the test results including pH, pCO₂, pO₂, HCO₃, O₂ Saturation, TCO₂ in the patient final report. b. The laboratory enrolled its pH, pCO₂, and pO₂ testing analyte which are in the list of subpart I with CAP (College of American Pathologists) PT programs approved by CMS CLIA programs. c. The patient tests report including HCO₃, O₂ Saturation and TCO₂ are not included in subpart I of 42 CFR part 493. d. The laboratory must verify, but failed to, at least twice annually, the accuracy of the test or procedure listed in (c) mentioned above which are NOT included in subpart I of 42 CFR part 493. d. The laboratory may enroll in a PT program or another alternative way to verify the accuracy of their test or procedure, at least twice annually.</p>
D5801	<p>TEST REPORT CFR(s): 493.1291(a)</p> <p>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</p>

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 review the laboratory reports and instrument print-out, and interview with the testing personnel (TP), it was determined that the laboratory failed to have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data were accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination including results and patient-specific data electronically reported to network or interfaced systems., The findings included: a. The laboratory implemented a new hospital computer system, Evidence, to provide EMR (electronic medical records) in June 2018, and interfaced with the laboratory instrument, ABL 80 flex Radiometer, a arterial blood gases instrument. b. Interviewed with the testing personnel and requested the TP to provide evidences how the tests results and other patient-specific data were accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination. c. The TP was not able to provide the acceptable evidences or print-out in a timely manners. d. of the patient the print out, to show how the instrument testing results were accurately and correctly interfaced/transmitted to the Evidence for EMR purpose. e. Review of a instrument print-out data indicated ID # "27862" and a patient report identified by the name of MidwXXX, ClaXX were provided without evidence how this ID # 27862 is from the sample of the patient's name identified on the report. f. The surveyor requested the evidences to provide the linkage between "27862" and MidwXXX, ClaXX. g. At the time of survey (10/24/18 @ 15:15) the TP was not able to print out and provide the acceptable linkage evidences between ID # and the patient's name on the final report. h. The TP called someone in IT (information system) for help, but failed before the surveyor left and no print out. i. Day later 10/25/18, the TP faxed to our LA office, copies of designated "Machine results that print out" with a patient information of "27862" and patient test result reports ("Ugly" report print to us, also in computer, "Pretty" report goes to doctor), which were identical at the time the surveyor reviewed. j. No NEW evidences to provide the linkage of "27862" results accurately interfaced to the patient final report, name of MidwXXX, ClaXX (purposely not to disclose full name).

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's records, and interview with the testing personnel

(TP), it was determined that the laboratory director failed to be 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 for assuring compliance with the applicable regulations. A qualified laboratory director may perform the duties of the technical consultant, clinical consultant, and testing personnel. The findings included: See D-5217, D-5801, D-6018, and D-6045

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 proficiency testing (PT) result reports, and interview with the testing personnel (TP), it was determined that the laboratory director (LD) failed to 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; The findings included: a. The laboratory performed arteriole blood gases using Radiometer ABL 80 flex and enrolled its PT evaluation of testing performance with CAP (College of American Pathologists). b. Review of the 3rd 2017 CAP PT and 1st 2018 CAP PT results scored reports, no evidences of the LD's review were noted . c. The laboratory director failed to ensure that all proficiency testing reports received were reviewed with the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;

D6045

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(7)

(b) The technical consultant is responsible for-- (b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed;

This STANDARD is not met as evidenced by:

Based on observations, review of the laboratory records, and interview with the testing personnel, it was determined that the laboratory consultant failed to identify training needs and assure that each individual performing tests received regular in-service training and education appropriate for the type and complexity of laboratory services performed. The findings included: See D-5801