

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0710557	(X3) Date Survey Completed 09/29/2021
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
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's policy & procedure and CAP proficiency testing (PT) records for the years of 2019, 2020 and 2021, and interview with the laboratory testing person #1 on September 29, 2021 at 11:35 am, the laboratory failed to attest the proficiency testing samples were integrated into the laboratory's routine workload. The findings include: 1. The laboratory successfully participated CAP proficiency testing program for the years of 2019, 2020 and 2021. However, it had no attested documentation showing that the testing person tested the PT samples by integration into the routine patient workload using the laboratory's routine method. The testing person #1 said that the PT samples were run by only the testing person #1 while there were 6 other testing persons performed patient sample testing. The samples must be tested with the laboratory 's regular patient workload by personnel who routinely perform the testing in the laboratory. PT samples are to be tested in the same manner as patient specimens. Handling PT sample differently and with special care than the patient sample might have doubtful result of the patient sample reported. 2. The laboratory testing person #1 on September 29, 2021 at 11:35 am, affirmed that the laboratory did not have any records of PT sample testing attestation. 3. The laboratory's testing declaration form, signed by the laboratory Director on 9/29/2021, stated that the laboratory performs 220 tests in blood gases, annually.</p>
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</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.

This STANDARD is not met as evidenced by:

Based on Surveyor review of laboratory's policy & procedure, lack of competency assessment documents, and interview with the laboratory testing person #1 on September 29, 2021 at 11:05 am, the laboratory failed to establish and follow written policies and procedures to assess testing personnel competency resulting lack of competency evaluation for all 7 testing personnel. The findings include: 1. The laboratory performed blood gas analyses using ABL-90 Flex instrument. There were 7 testing persons in the laboratory. However, the laboratory did not have any documentation showing that it had evaluated competency of testing persons. The procedures for evaluation of the competency of the staff must include i) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing; ii) Monitoring the recording and reporting of test results; iii) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records; iv) Direct observation of performance of instrument maintenance and function checks; v) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and vi) Assessment of problem solving skills. Testing of patient sample by incompetent testing persons might have incorrect results reported. 2. The laboratory testing person #1 on September 29, 2021 at 11:05 am, affirmed that the laboratory did not evaluate competency of its testing persons. 3. The laboratory's testing declaration form, signed by the laboratory Director on 9/29/2021, stated that the laboratory performs 220 tests in blood gases, annually.

D6016

LABORATORY DIRECTOR RESPONSIBILITIES

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

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)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:

Based on Surveyor review of laboratory's policy and procedure, proficiency testing records for the years of 2019, 2020 and 2021, and interview with the laboratory testing person #1 on September 29, 2021 at 11:35 am, the laboratory director failed to assure that the proficiency testing samples were tested as in the same manner of patients' samples. The findings include: See D2009.

D6029

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(11)

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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:
Based on Surveyor review of laboratory's policy and procedure, lack of training and competency assessment records, and interview with the laboratory testing person #1 on September 29, 2021 at 11:05 am, the laboratory director failed to ensure laboratory staffs are performing the test methods as required for accurate and reliable results. The findings include: See D5209.

D6046

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

(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.

This STANDARD is not met as evidenced by:
Based on Surveyor review of laboratory's policy & procedure, lack of competency assessment documents, and interview with the laboratory testing person #1 on September 29, 2021 at 11:05 am, the technical consultant failed to evaluate all 7 testing personnel competency. The findings include: 1. The laboratory performed blood gas analyses using ABL-90 Flex instrument. There were 7 testing persons in the laboratory. However, the laboratory did not have any documentation showing that it had evaluated competency of testing persons. Testing of patient sample by incompetent testing persons might have incorrect results reported. 2. The laboratory testing person #1 on September 29, 2021 at 11:05 am, affirmed that the technical consultant did not evaluate the competency of any testing person. 3. The laboratory's testing declaration form, signed by the laboratory Director on 9/29/2021, stated that the laboratory performs 220 tests in blood gases, annually.