Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0064137	10/24/2018
Name of Provider or Supplier	**Street Address, City, State**	
Orchard Hospital Laboratory	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
D2087	ROUTINE CHEMISTRY CFR(s): 493.841(a) 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. This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing (PT) result reports, and interview with the laboratory manager (LM), it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event was unsatisfactory analyte performance for the testing event. The findings included; a. The laboratory used Vitros Model 5600 to perform routine chemistry, including, but are not limited to the followings: Albumin, ALT, Na, Calcium and Glucose.. b. The laboratory enrolled its proficiency testing programs with API (American Proficiency Institute) to evaluate the proficiency testing performance of its testing systems. c. The laboratory attained scores of 40 % and 20 % for the analyte, Na and ALT in the 1st and 3rd 2017 chemistry PT events, respectively, which were unsatisfactory analyte performance for the testing events. d. The laboratory performed Na, and ALT in approximately 410 patient samples for each of both test monthly. e. The laboratory manager affirmed (10/24/2018 @ 12:34 PM) that the laboratory attained scores of 40 % and 20 % for the analyte, Na and ALT in the 1st and 3rd 2017 chemistry PT events, respectively, which were unsatisfactory analyte performance for the testing events.
D3001	FACILITIES CFR(s): 493.1101(a)(1) The laboratory must be constructed, arranged, and maintained to ensure the space, ventilation, and utilities necessary for conducting all phases of the testing process.

	This STANDARD is not met as evidenced by: Based on observation of the facility, and interview with the laboratory manager (LM), it was determined that the laboratory failed to provide, construct, arrange, and maintain to ensure the space, and utilities necessary for conducting all phases of the testing process. The findings included: a. The laboratory facility is located in approximately 830 square feet inside of the hospital building. b. The laboratory performed various subspecialty and specialty including bacteriology, parasitology, general immunology, routine chemistry, urinalysis, endocrinology, toxicology, hematology, blood bank with transfusion services, and provides frozen section histology. c. The laboratory performed all phases identified above in approximately 267,342 total patient test volume annually plus send/out logistics services. d. Observed the personnel working conditions, movements within the laboratory facility, and various equipments layout , it appeared to the surveyor that the laboratory did not provide sufficient space for the laboratory operations. e. Inadequate working space may compromise the quality and performance of the laboratory operations.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory quality control (QC) documents, and interview with the laboratory manager (LM), it was determined that the laboratory failed to follow written control procedures to monitor the accuracy and precision of the complete analytic process to detect immediate errors that occur due to operator performance and to monitor over time the accuracy and precision of test performance that may be influenced by any variance in operator performance. The findings included: I. a. The laboratory is a hospital setting laboratory provided blood banking with transfusion services. b. Review of the laboratory's "ORCHARD HOSPITAL BLOOD BANK GEL SCHEMATA" records, from September 21, 2018 thru October 24, 2018. c. A QC Run Date on 09/27/2018 @0930, the document of "Pos AB Screen" recorded incorrectly for a Positive antibody screen QC with "0" (Negative" test results. d. The "Pos AB Screen" record showed incorrect results between its "Expected Result" and "Actual Result". e. The results for Sc Cell I, Sc Cell II, Sc Cell III and Conf Cell 2 dil to 0.8% were recorded as "0" (Negative) for all 4 Cells reagents, which was incorrect for the Positive AB Screen QC came out all NEGATIVE.. The EXPECTED QC results must be "POSITIVE".. II. a Review of two "ORCHARD HOSPITAL BLOOD BANK GEL SCHEMATA" records run on 10/08/18 @1200 PM and 10/9/18 @2300. b. The MTS Dil2 Plus reagent Lot # MDP160, one testing personnel (TP) recorded on the run day of 10/08/18 indicated Exp Date 2019-02-06, while the other TP run day on 10/9/18 @2300 recorded the identical MTS Dil 2 Plus reagent with same Lot #

	MDP 160 BUT different Exp Date of 2-26-2019. c. The laboratory failed to detect the errors of QC records and failed to evaluate the testing personnel competencies..
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 review of the laboratory quality control (QC) documents, and interview with the laboratory manager(LM), it was determined that the laboratory failed to follow written control procedures to effectively monitor the accuracy and precision of the complete analytic process to detect immediate errors that occur due to operator performance and to monitor over time the accuracy of test performance that may be influenced by any variance in operator performance. The findings included: See D-5441
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of the laboratory patient test result reports and interview with the laboratory manager, it was determined that the laboratory's patient test reports did not properly provide and indicate the test results with interpretations between genders. The findings included: a. The laboratory implement a new hospital information system, Evidence, which is interfaced with the laboratory information system and analyzers. b. The laboratory used Coulter DxH to report CBC including WBC (white blood cell) with cell differentials, RBC (red blood cell), Hemoglobin (Hgb), Hematocrit (Hct) and Platelet counts. c. There are different normal ranges between males and females for RBC, Hgb, and Hct. d. Review patient CBC test result reports, ID 163781 (M,T 2/11/1972 DOB), a female specimen was collected and performed on 9/10/2017. e. Review patient CBC test result reports, ID 10008332 (A,S 06/29/73 DOB), a male specimen was collected and performed on 10/10/2018. f. Review patient CBC test result reports, ID 10009341 (S,D 02/03/71 DOB), a female specimen was collected and performed on 10/24/2018. g. The laboratory provided identical normal ranges for RBC between 3.83 to 5.08; Hgb 11.5 to 15.5; and Hct 34.5 to 46.3. for all three patient reports in different genders for either males or females. h. The

	laboratory manager affirmed (10/24/18 @ 13:10) that laboratory failed to provide proper normal ranges for RBC, Hgb, and Hct in CBC patient hematology reports based on the gender difference .
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 patient test result reports, and interview with the laboratory manager, it was determined that the laboratory failed to effectively follow written policies and procedures for an ongoing mechanism to review, to monitor, and assess the patient test result reports for quality assessment and failed to ensure and provide the patient test reports with appropriate and correct interpretations for hematology testing between genders. The findings included: See D-5805
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 observation of the facility, review of the laboratory documents, and interview with the laboratory manager and the laboratory director, it was determined that the laboratory director failed to be responsible for overall operation and for assuring compliance with the applicable regulations. The findings included: See D-3001, D-6016, and D-6021
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 review of the laboratory's proficiency testing (PT) result reports, and interview with the laboratory manager, it was determined that the laboratory director failed to ensure that the proficiency testing samples were tested as required under Subpart H of 42 CFR part 493. The findings included; See D-2087
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 observation of the facility, review of the laboratory documents, and interview with the laboratory manager, it was determined that the laboratory director failed to ensure that quality assessment programs were established and maintained to assure the quality of laboratory services provided.. The findings included: See D-5791, and D-5891