Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0644257	07/30/2021
Name of Provider or Supplier	**Street Address, City, State**	
Trinity Hospital Lab	60 Easter Ave, Weaverville, 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 records and the proficiency testing (PT) result reports, and interview with the laboratory personnel (TP), 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 is in an acute care hospital, performed various chemistry testing including but not limited to pCO2. b. To ensure the accuracy of the testing results, the laboratory enrolled the routine chemistry PT with American Proficiency Institute (API) PT program. c. The laboratory attained a score of 20% for pCO2 in the Q2 2021, which was unsatisfactory performance in the PT events. e. The laboratory staff affirmed (7/30/21) that the laboratory attained score of 20% for pCO2 in the Q2 2021 PT, which was unsatisfactory performance in that PT events.
D2121	HEMATOLOGY CFR(s): 493.851(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 records and the proficiency testing (PT) result reports, and interview with the laboratory personnel (TP), 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 is in an acute care hospital, performed hematology including coagulation testing. b. To ensure the accuracy of the testing result, the laboratory enrolled its PT with American Proficiency Institute (API) PT programs for hematology testing performed. c. The laboratory attained a score of 0 % for Prothrombin Time (PTn) in the Q2 2020 PT event, which was unsatisfactory performance for the PT events. d. The laboratory personnel affirmed (7/30/21) that the laboratory attained a score of 0% for PTn in Q2 2020 PT event was unsatisfactory performance for that event. e. The laboratory performed and reported the PTn results in approximately 67 patient samples each month.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) 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. This STANDARD is not met as evidenced by: Based on review of the laboratory's records and the proficiency testing (PT) result reports, and interview with the laboratory personnel (TP), it was determined that the laboratory, at least twice annually, failed to verify the accuracy of any test or procedure it performed that is not included in subpart I of 42 CFR part 493. The findings included: a. The laboratory is in an acute care hospital, performed various laboratory testing including but are not limited to the followings: Ammonia, CA-19-9, CRP (hs), HA1C, Lipase, Progesterone (Prog), Testosterone (TST), Troponin (Tpn), TIBC, which are NOT in the list of subpart I of 42 CFR of part 493. b. To ensure the accuracy of the testing results, the laboratory elected to enroll the analyte listed in the item (a) above, which the laboratory performed NOT in the list of subpart I of 42 CFR part 493, for the evaluation of proficiency testing performance with American Proficiency Institute (API) PT programs. c. The laboratory failed to attained scores of 80 % for the analyte listed in the item (d) below, were unsatisfactory performance for the PT events. d. The laboratory failed to attain at least 80% for each analyte in a PT event was unsatisfactory performance for that event, see below: Test/% = test name /graded score in % Qx/Event = Q1 thru Q3/year Qx/Event Test/% Test/% Test/% Q3 2019 CRP(hs)/50 Tpn/40 Q2 2020 Ammonia/67 Prog/50 Q3 2020 CA-19-9/60 TST /50 A1C/60 BNP/20 TIBC/60 Q1 2021 CA19-9/60 Q2 2021 Lipase/60 e. The laboratory performed the analyte identified in the item (d) above in approximately patient samples volume per month in the format of test/volume. CRP(hs)/1 Ammonia /7 Lipase /51 CA19-9/2 TST/11 A1C/82 BNP/45 Tpn/67 f. The laboratory staff affirmed (7/30/21) that the laboratory failed to attain a score of 80% for each analyte listed in the item (d) were unsatisfactory performance for the PT events.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.

	This STANDARD is not met as evidenced by: Based on touring the laboratory facility, review of the laboratory records, and interview with the laboratory personnel and the hospital contracted IT (Information Technology) personnel, it was determined that the laboratory must select the test (alarm for transfusion service) systems properly to ensure and provide the accuracy, reliability, and timely test (alarm for transfusion service) system operated and performed to meet the expectations. It was determined that the laboratory failed to establish a newly installed alarm system for Blood Bank's transfusion services including whom/what/how an alarm system to be activated, alerted, and warned, so to assure the laboratory personnel to take actions immediately and accordingly when the temperature of the storage equipment out of acceptable/optimal temperature range failed, and to ensure that the quality of blood products are maintained at all time, in a manner that provides test results (alarm system) operated within the laboratory's stated performance specifications and expectations. The findings included: a. The laboratory is in an acute hospital and provided various laboratory testing including transfusion services with quality blood products. b. The laboratory has newly installed an alarm system to provide immediate warning for the failure of the temperature-controlled storage equipment, and to assure the laboratory take immediately actions to maintain the quality of the blood products in storage. c. Based on interview with the laboratory personnel and the contracted IT personnel, currently the warning systems due to the failure of the temperature system is that the IT department would initiate and generate an email to notify a laboratory personnel, who may or may not in the laboratory, to take actions immediately and to correct the failure or provide alternative ways to assure the quality of the blood products are maintained. d. Based on interview with the laboratory personnel (TP), the better ways of warning of temperature failure is to have a warning system, activated directly to a nursing station which immediately alert the laboratory, (if the laboratory personnel was not aware), and/or plus generate an email by the IT department to designated personnel to assure an immediately and effective actions taken to ensure the quality of the blood products maintained. e. At the time of survey (7/30/21 @ 11:45 am) that there were no acceptable warning systems established and agreed within the concerned personnel including the hospital administration, the laboratory, and the IT, other than the IT send-out an "email" notification. f. The laboratory must select the effective, workable, and appropriate systems as how to immediately and effectively notify the personnel involved to take actions when the temperature of the blood products storage equipment failed and to assure the quality of the blood products maintained.
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 records and the proficiency testing (PT) result reports, and interview with the laboratory personnel (TP), it was determined that the laboratory director failed to ensure that the proficiency testing samples were tested as required. The findings included: a. The laboratory is in an acute care hospital,

	performed various laboratory testing which are in the list or NOT in the list of subpart I of 42 CFR part 493. b. The laboratory enrolled its PT with American Proficiency Institute (API) PT programs for all its testing analyte c. The laboratory failed to attain a score of 80 % for analyte listed in 42 CFR part 493 which constitute an unsatisfactory performance for that PT events, see D-2089 and D-2121. d. The laboratory failed to attain a score of 80 % for analyte NOT listed in 42 CFR part 493 which constitute an unsatisfactory performance for the evaluation of proficiency testing performance by the PT events, see D-5217.
D6023	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(6) 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)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system; This STANDARD is not met as evidenced by: Based on touring the facility, review of the laboratory's records and the proficiency testing (PT) result reports, and interview with the laboratory personnel (TP) and the hospital contracted IT personnel, it was determined that the laboratory director failed to ensure the establishment and maintenance of acceptable levels of analytical performance for each test system. The findings included: a. 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 is, see D-2087, D-2121 and D-5217. b. The laboratory must select the testing systems which would provide and assure for accuracy, reliability and timely of the testing(alarm system in transfusion service) systems laboratory operated, see D-5411.