Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0700348	06/06/2019
Name of Provider or Supplier	**Street Address, City, State**	
Riverside Community Hospital	4445 Magnolia Ave, R3, Riverside, 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
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 review of the laboratory patient test reports from the laboratory information system (LIS) and the electronic hospital record system (EHR), and interview with the laboratory personnel and the supervisor. it was determined that the laboratory failed 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. The findings included as follows: a. Reviewed the "Patient Report" printed from the laboratory's LIS, which the laboratory personnel used to verify the accuracy of their patient results before releasing the reports. b. The "Patient Report" from LIS showed the reference values for ctHb (hemoglobin) were the same, 12.0 -18.0, for both genders, male or female, which were inappropriate and inaccurate for blood hemoglobin reference values. c. The normal hemoglobin level for female is different from male. d. Review of the patient report from EHR showed that the female reference range for ctHb was 12.0 to 16.0, which was appropriate. e. The laboratory failed to ensure that 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. e. The laboratory personnel affirmed (6/6/19 @ 12:10 PM) that the laboratory failed 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.
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's patient test result reports, and interview with the laboratory personnel and the supervisor, it was determined that the laboratory failed to indicate the test report date in the final patient test result reports appropriately. The findings included: a. Reviewed the patient final test report, Acct #: AD0228993300, printed from EHR. b. This report showed COLL: 6/1/19 - 0545, and RECD: 06/01/19 - 0624, and ENTERED: 06/01/19 - 0545 c. This ENTERED: 06/01/19 - 0545 timing was exactly identical with COLL: 6/1/19 - 0545. d. The supervisor affirmed that the "ENTERED" was to indicate when order placed by an ordering personnel. The "RECD" indicated the specimen received by the laboratory. e. Under a "Verified" column showed 06/01/19 - 0625 for all the ABG (arterial blood gas) test results on the report. f. The laboratory supervisor stated that the test report date was 6/1/19 -0625 under "Reviewed" column. g. The laboratory did not have "REPORTED" a wording commonly used to indicate clearly that was "the test report date", in the patient test reports. h. CLIA regulation CFR 493.1291(c)(3) states: A test report date is "the date results were generated as a final report and must not change on copies generated at a later date."
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 reports from the laboratory information system (LIS) and records, and interview with the laboratory personnel and the supervisor. it was determined that the laboratory failed to follow written policies and procedures for an ongoing mechanism to monitor, assess the post-analytic system, to assure the accuracy of the test reports, and when indicated, correct problems identified. The findings included as follows: a. See D-5801, S-5805, and b. Reviewed the patient testing records, Account number 302866, a "Patient Report" generated by LIS, and a copy of "Blood Gas Analysis" pre-analytic test order. c. The ordering person marked for venous blood to be drawn from the patient on the pre-analytic order. d. The Patient Report generated by LIS indicated that the "Sample Type" was

	Blood ARTERIAL. e. There was inconsistent information noted between specimen collected and sample type been performed. f. The laboratory supervisor affirmed (6/6 /19 @ 11:45 AM) that the laboratory had established written policies and procedures to require each testing person reviewed and verified the accuracy of the testing results and other patient-specific data were accurately and reliably before releasing the report. g. The laboratory personnel failed to effectively follow the written policies and procedures to assure the reviewing the accuracy of all test result report with other patient information.
D5893	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(b)(c) (b) The postanalytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of postanalytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all postanalytic systems quality assessment activities. This STANDARD is not met as evidenced by: Based on review of the laboratory patient test reports from the laboratory information system (LIS) and records, and interview with the laboratory personnel and the supervisor. it was determined that the laboratory failed to review the effectiveness of the established written quality assessment policies and procedures in taking on corrective actions to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of post-analytic systems quality assessment reviews with appropriate staff. The findings included as follows See D-5891
D6024	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(7) 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)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified, This STANDARD is not met as evidenced by: Based on review of the laboratory patient test reports from the laboratory information system (LIS) and records, and interview with the laboratory personnel and the supervisor. it was determined that the laboratory director failed to ensure that all necessary remedial actions were taken and documented whenever significant deviations from the laboratory's established performance specifications were identified, The findings included as follows See D-5893
D6025	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(7) 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)(7) Ensure that patient test results are reported only when the system is functioning properly. This STANDARD is not met as evidenced by: Based on review of the laboratory patient test reports from the laboratory information system (LIS) and records, and interview with the laboratory personnel and the supervisor. it was determined that the laboratory director failed to ensure that patient test results were reported only when the system is functioning properly. The findings included as follows" See D-5893