Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0270892	01/17/2019
Name of Provider or Supplier	**Street Address, City, State**	
Baptist Hospital Laboratory	123 Baptist Way, Pensacola, FL	

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
D0000	A complaint survey was conducted on January 17, 2019. Baptist Hospital Clinical Laboratory was not in compliance with 42 CFR 493, requirements for laboratories. Three CLIA Conditions were not met at the Immediate Jeopardy level: 42 CFR 493.1100 Facility Administration , 42 CFR 493.1250 Analytic Systems and 42 CFR 493.1441 Laboratory Director for High Complexity Testing. Immediate Jeopardy was identified as beginning on July 29, 2018 and is presently ongoing.
D3000	FACILITY ADMINISTRATION CFR(s): 493.1100 Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe. This CONDITION is not met as evidenced by: Based on facility policy review, patient record review, and staff interview, the laboratory failed to ensure compliance with the requirement for reporting to the authorities on a patient who had a hemolytic transfusion reaction which resulted from a tech error to perform an antibody identification work up and led to the wrong issuance of a unit of blood to the patient (refer to D3025). The effect of the failure for reporting this event resulted in the hospital's patient not properly investigated and the error not fully corrected.
D3025	REQUIREMENTS FOR TRANSFUSION SERVICES

	CFR(s): 493.1103(d) Investigation of transfusion reactions. The facility must have procedures for preventing transfusion reactions and when necessary, promptly identify, investigate, and report blood and blood product transfusion reactions to the laboratory and, as appropriate, to Federal and State authorities. This STANDARD is not met as evidenced by: Based on record review and interview, it was determined that the laboratory did not ensure compliance with the authorities to report transfusion reaction related incidents due to the laboratory's error to detect the antibody before the issuance of blood. A patient who developed a hemolytic transfusion reaction was not reported. Findings included: A review of the blood or blood bank records showed that a unit of blood (Unit # W036818596259) was transfused on 9/27/18 to patient # A. The patient developed a transfusion reaction after a unit of blood was transfused. It was found out that the patient was transfused with a unit of blood positive with Jkb antigen. Record review of patient antibody test result showed anti Jkb and anti D. It was determined that the type of the transfusion was hemolytic. There was no document to show that it was reported to FDA. The patient had developed hemolytic transfusion reaction due to a unit of blood that was issued and transfused on 7/29/18 positive with Jkb antigen. The antibody work up was not done before the release of the unit. Interview on 1/17 /19 at 11:00 AM, the blood bank manager confirmed that the laboratory was not aware of the policy to report to FDA for a situation when the incorrect unit of blood was issued and transfused. The laboratory stated that according to the latest edition of the American Association of Blood Bank Manual. 19th edition, the only type of hemolytic transfusion reaction that must be reported is a fatality. On page 592, " When the death of a patient results from a reaction to or complication of a transfusion, current regulations require that the fatality be reported to the FDA by the facility that performed the compatibilty testing."
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on facility policy review, patient record review , and staff interview, the laboratory failed to ensure compliance with the requirement for following laboratory's written procedures to correctly perform and report patient antibody screen, identification and compatiblity testing for blood transfusion. The noncompliance resulted in an acute hemolytic transfusion reaction for a patient # A(refer to D5401).
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the

	laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on facilty policy review , patient record review, and staff interview, the laboratory failed to ensure that testing personnel followed written procedures to correctly perform antibody identification work up on a patient with positive antibody screen test result. Findings included: Review of the hospital's report of transfusion on a patient # A showed that blood bank technologist # 1 failed to perform the blood bank procedure for the antibody identification work up when a positive test result for antibody screen from the day shift was performed. This resulted to the development of a hemolytic transfusion reaction of the patient. The previous specimen on a first sample was reported as positive by the tech on a day shift. Night shift asked for a second sample to the floor due to a specimen that was short from a previous sample and the new specimen was performed for the antibody screen again and reported it as negative which resulted into an antibody identification not done. Send out to the reference lab (One Blood) was found out that patient had an anti Jkb and anti D. A unit of blood positive with Jkb antigen was transfused to the patient on 7/29/18.. Review of the policy of the laboratory on 1/17 19, policy number 25.70 stated that if positive reactions are observed in any phase of the test, the antibody screen is positive and identify following Antibody Identification listed under the Technical Procedures. This was not performed by tech # 1. During an interview on 1/17/19 at 10:30 AM, the laboratory manager confirmed that the sample which was previously tested positive for antibody screen on 7/29/18 was not continuedly tested into antibody identification. The tech error led to the development of a hemolytic transfusion reaction on the patient.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on facility policy review, patient record review and staff interview, the laboratory director failed to meet the responsibility of ensuring that testing personnel followed written procedures for reporting accurate and reliable test results. The noncompliance resulted in a hemolytic transfusion reaction of a patient (refer to D6087).
D6087	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(iii) The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory director failed to ensure

	that testing personnel # 1 followed written procedures for reporting accurate and reliable antibody screen results for a patient involved in a transfusion reaction. The antibody work up was not done before the unit of blood was issued. Findings included: Review of the patient's blood bank document and results indicated that on 7 /29/18, the patient was first positive for antibody screen reported from the day shift tech . Subsequent request of a new sample by the night shift due to a short sample was reported as negative and resulted to an antibody identification work up testing not done and wrong unit of blood was transfused. The tech did not follow the laboratory's policy to proceed into antibody identification when patient # A did tested positive for antibody screen on a first sample. Interview on 01/17/19 at 11:30 AM, the blood bank manager confirmed that retesting the pre-transfused sample concluded that screen was conclusively positive in addition to units were incompatible and the sample was not properly identified for antibodies. Interview at 1:30 PM, the lab director said that when the event happened on 7/29/18 at night shift, a pathologist was notified in the hospital. Review of the documents indicated that there was no specific corrective action done from the erroneous report of the patient test result. There was no policy instituted for discrepancies of testing patient test results in the antibody screen. The laboratory did not create and perform the root cause analysis to identifiy the problem.