Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0053438	08/26/2019
Name of Provider or Supplier	**Street Address, City, State**	
Hca Houston Healthcare Conroe	Laboratory Department, 2nd Floor, Conroe, TX	

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	An unannounced investigation of complaint TX00322871 was conducted on site on 8 /26/19, 9/11/19-9/12/19. Two of three allegations were substantiated and condition level deficiencies were cited. The laboratory was found out of compliance with the CLIA regulations. The conditions not met were: D3000 - 42 C.F.R. 493.1100 Condition: Facility Administration D5300 - 42 C.F.R. 493.1240 Condition: Preanalytic systems; D6076 - 42 C.F.R. 493.1441 Condition: Laboratories performing high complexity testing; laboratory director; The facility representative was given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit.
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 review of the hospital transfusion services, the facility administration failed to meet the requirements specified in 493.1101 through 493.1105. Refer to D3021 and D3023
D3021	REQUIREMENTS FOR TRANSFUSION SERVICES CFR(s): 493.1103(c)(1)

	Blood and blood products storage and distribution. If a facility stores or maintains blood or blood products for transfusion outside of a monitored refrigerator, the facility must ensure the storage conditions, including temperature, are appropriate to prevent deterioration of the blood or blood product. This STANDARD is not met as evidenced by: Based on review of laboratory policies, laboratory records, patient records, and confirmed in interview, the laboratory failed to ensure expired fresh frozen plasma (FFP) were stored separate from the routine inventory to prevent transfusion of expired blood products. Findings were: 1. Review of the laboratory policy Blood Products: Adminstration (policyStat ID 4235369, approved 12/2017) revealed "verify the patient and blood product identification data: patient name and hospital number, ID bracelet barcode ransfusion number, blood unit number, blood type - ABO and Rh, expiration date of the blood product." 2. Review of the FDA MedWatch Form FDA 3500 (10/18) revealed the facility made a voluntary reporting of adverse event for the 4 units of expired FFP that was transfused to a patient on 5/4/19. Patient Acct Number BH9024972457 Unit numbersW204919401529, exp 5/3/19 W200219615021, exp 5/3 /19 W204919396228, exp 5/3/19 W200219614439, exp 5/3/19 3. Review of the patient test records and corresponding blood bank unit inquiry records revealed that the above units of FFP were transfused to patient BH9024972457 on 5/4/19. 4. An interview with the laboratory manager on 9/12/19 at ? hours in the office confirmed the above findings. She acknowledged that the tech and nurse should have verfied the expiration date of the FFP units. She also stated that the laboratory should have discarded prior to the unit's expiration. She stated that currently the laboratory is working on a new lab policy to have each shift take inventory of all blood products in the routine inventory.
D3023	REQUIREMENTS FOR TRANSFUSION SERVICES CFR(s): 493.1103(c)(2) The facility must establish and follow policies to ensure positive identification of a blood or blood product recipient. This STANDARD is not met as evidenced by: Based on review of the laboratory policy, laboratory blood bank records, and confirmed in interview, laboratory failed to follow its policy to ensure positive identification of a blood or blood product recipient. Findings were: 1. Review of the laboratory policy Blood Bank Specimens - Routine Collection and Handling (736. PH211.032.4) revealed under specimen verification"verify that the specimen collection label has the correct patient identification information, (last name, first name, and MR number) collector's 3-4 ID (B. Lab for phlebotomist), date and time of collection." 2. Review of the laboratory policy Blood Products: Administration (policyStat ID 4235369, approved 12/2017) revealed "verify the patient and blood product identification data: patient name and hospital number, ID bracelet barcode transfusion number, blood unit number, blood type - ABO and Rh, expiration date of the blood product." 3. Review of the manual deviation report # 18188 revealed a blood bank specimen that was labeled with a blood bank tube number BB29 (which corresponds to patient BH9025170119) but with a chart label for a different patient (BH1131809605). 4. Review of patient test records for BH9025170119 revealed 1 unit of RBC was crossmatched (unit # W200219651057) and transfused on 8/11/19,

	despite having conflicting specimen identification on the specimen tube. 5. An interview with the laboratory manager on 9/12/19 at 1040 hours in the office confirmed the above findings. She stated that the nurse and laboratory techs did not follow the facility and lab policy and should have verified the specimen identification prior to collection and testing.
D5300	PREANALYTIC SYSTEMS CFR(s): 493.1240 Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in 493.1241 and 493.1242, 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 preanalytic systems and correct identified problems as specified in 493. 1249 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on facility policy, laboratory records, and confirmed in interview, the laboratory failed to meet the requirements of preanalytical systems. Refer to D5311.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on review of the laboratory and facility policies, laboratory records, and confirmed in interview, the facility failed to follow its policy for blood bank specimen collection. Findings were: 1. Review of the laboratory policy Blood Bank Specimens - Routine Collection and Handling (736.PH211.032.4) revealed under specimen verification"verify that the specimen collection label has the correct patient identification information, (last name, first name, and MR number) collector's 3-4 ID (B. Lab for phlebotomist), date and time of collection." 2. Random review of the manual deviation reports from 02/2019 to 06/2019 revealed the following specimen collection errors: 1) manual deviation 41880, date 2/21/19: "blood bank tub[e] came down to lab with no label just BB [blood bank] tail in a yellow with a labeled green & lav [tube] 2) manual deviation 41881, date 2/9/19: "blood bank wristband number on patient did not match blood bank number placed on tube or in computer." 3) manual deviation 43049, date 6/9/19: "[patient acct BH9025172042] wrist band T429965 BB [blood bank] tube labeled with above chart label [patient acct BH9025149996] 4) manual deviation 42104, date 3/13/19: "blood bank sample labeled incorrectly. Only patient name printed on label." 5) manual deviation 41822, date 2/15/19: "blood bank armband had no initials, collection date, or collection time." 6) manual deviation 42417, date 4/27/19: "1st sample mislabeled. No 3-4 ID." 7) manual deviation 42489, date 5/7/19: "BB specimen not labeled correctly, requested redraw." 8) manual deviation 41885, date 2/9/19: "blood bank ID number on tube did not match BB

	[blood bank] number in meditech [facility laboratory information system]" 9) manual deviation 42537, date 5/9/19: "improperly labeled - no time, requested redraw (3-4 ID: GOC9621). 2nd redrawn specimen has no BB band #. Requested another redraw." 10) manual deviation 42563, date 5/14/19: "blood bank specimen sent with no 3/4 Id and it was double labeled (2 [patient] chart labels, one on top of the other so that we were unable to verify that both labels were for the same patient.)" 3. An interview with the lab manager on 9/12/19 at 0935 hours in the office confirmed the above findings. She stated that the laboratory is working on retraining the staff for proper specimen collection, especially for blood bank.
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(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 preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on review of the laboratory policies, laboratory records, and confirmed in interview, the laboratory quality assessment policies failed to monitor and correct problems in the preanalytic systems. Findings were: 1. Review of the laboratory policy Blood Bank Specimens - Routine Collection and Handling (736.PH211.032.4) revealed under specimen verification"verify that the specimen collection label has the correct patient identification information, (last name, first name, and MR number) collector's 3-4 ID (B. Lab for phlebotomist), date and time of collection." 2. Random review of the manual deviation reports from 02/2019 to 06/2019 revealed the following specimen collection errors: 1) manual deviation 41880, date 2/21/19: "blood bank tub[e] came down to lab with no label just BB [blood bank] tail in a yellow with a labeled green & lav [tube] 2) manual deviation 41881, date 2/9/19: "blood bank wristband number on patient did not match blood bank number placed on tube or in computer." 3) manual deviation 43049, date 6/9/19: "[patient acct BH9025172042] wrist band T429965 BB [blood bank] tube labeled with above chart label [patient acct BH9025149996] 4) manual deviation 42104, date 3/13/19: "blood bank sample labeled incorrectly. Only patient name printed on label." 5) manual deviation 41822, date 2/15/19: "blood bank armband had no initials, collection date, or collection time." 6) manual deviation 42417, date 4/27/19: "1st sample mislabeled. No 3-4 ID." 7) manual deviation 42489, date 5/7/19: "BB specimen not labeled correctly, requested redraw." 8) manual deviation 41885, date 2/9/19: "blood bank ID number on tube did not match BB [blood bank] number in meditech [facility laboratory information system]" 9) manual deviation 42537, date 5/9/19: "improperly labeled - no time, requested redraw (3-4 ID: GOC9621). 2nd redrawn specimen has no BB band #. Requested another redraw." 10) manual deviation 42563, date 5/14/19: "blood bank specimen sent with no 3/4 Id and it was double labeled (2 [patient] chart labels, one on top of the other so that we were unable to verify that both labels were for the same patient.)" 3. Review of the facility policy Patient Safety and Risk Management Plan revealed "recognition and acknowledgement of the potential for medical/health errors and/or injuries and risks to patient safety; initiation of actions to reduce these risks; internal reporting of what has been found and the actions taken; process and system focused corrections to reduce related failures including thorough and credible Serious Event Analysis and routine Failure Mode and Effects/Criticality Analysis." 4. Review of the above manual deviations revealed no documentation of corrective actions for the mislabeled specimens. 5. An interview with the Vice President of Quality on 9/12

	/19 at 0945 hours in the office confirmed the above findings. She stated that the "follow-up" to incidents reported falls under each department.
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 review of the facility records and staff interview, it was revealed the laboratory director failed to provide overall management for the laboratory. Refer to D6082 and D6094
D6082	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1) The laboratory director must ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing. This STANDARD is not met as evidenced by: Based on review of laboratory's policy and patient transfusion records, the laboratory director failed to ensure that blood component transfusion practices provided quality laboratory services, as evidenced by: 1. The facility failed to ensure positive identification of patient's specimen prior to receiving blood products. Refer to D3023. 2. The laboratory failed to ensure expired fresh frozen plasma (FFP) were stored separate from the routine inventory to prevent transfusion of expired blood products. Refer to D3021 3. The laboratory failed to follow written policies for sample preparation, collection, and labeling for recipients of blood and/or blood components. Refer to 5311.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of the facility records and confirmed in interview, the laboratory director failed to ensure a quality assessment plan identified and corrected problems. Refer to D5391