Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0658153	08/14/2019
Name of Provider or Supplier	**Street Address, City, State**	
Lab Clin Hosp San Carlos Borromeo	550 Concepcion Vera Ayala, Moca, PR	

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
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 blood bank (BB) policies records, BB quality assessment records (years 2018-2019), BB blood component utilization records (2019) and interview with the general supervisor on August 14, 2019 at 10:30 AM, it was determined that the BB failed to ensure that the transfusion reactions were promptly identify since April 11, 2017. The findings include: 1. On August 14, 2019 at 10:30 AM, the blood bank policies records showed that the BB approved procedures for blood and blood component transfusions on April 11, 2017. However, the procedures did not include how the BB assure that all blood transfusion were evaluate to promptly identify the transfusions reaction. 2. The BB quality assessment records showed that the BB evaluate monthly one blood transfusion records since January 2019. 3. The general supervisor confirmed on August 14, 2019 at 10:30 AM, that the blood transfusion procedures did not include how the BB assure that all blood transfusion were evaluate to promptly identify the transfusions reaction. She stated that the information system detect the completeness of the blood transfusion information records but , not detect vital or physiological patients changes. She also confirmed that the BB evaluate monthly one blood transfusion records. 4. The BB blood component utilization records showed that the BB utilized 697 blood components from January 2019 to July 2019 and one transfusion reaction was detected in March 2019.
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 blood bank (BB) procedures manuals review and interview with the general supervisor on August 14, 2019 at 10:30 AM, it was determined that the BB failed to have a written procedure to ensure that the temperature of the blood unit was maintained if the blood unit is returned to the blood bank since January 2019. The findings include: 1. On August 14, 2019 at 10:30 AM, the blood bank procedures manual did not include a written procedure to ensure that the temperature of blood unit was maintained if the blood unit is returned to the blood bank since January 2019. 2. The general supervisor confirmed on August 14, 2019 at 10:30 AM, that the BB did not have a procedures to monitor the temperature of blood unit if the blood unit is returned to the BB. She stated and showed the transfusing records that no blood units were returned since January 2018. 3. The BB blood component utilization records showed that the BB utilized 697 blood components from January 2019 to July 2019.
D5405	PROCEDURE MANUAL CFR(s): 493.1251(c) Manufacturer's test system instructions or operator manuals may be used, when applicable, to meet the requirements of paragraphs (b)(1) through (b)(12) of this section. Any of the items under paragraphs (b)(1) through (b)(12) of this section not provided by the manufacturer must be provided by the laboratory. This STANDARD is not met as evidenced by: Based on Rapid Lab 1200 manufacturer's instruction , blood gases quality control records review from January 2018 to August 14, 2019 and testing personnel interview on August 14, 2019 at 11:26 AM, it was determined that the laboratory failed to follow the manufacturer's instruction for calibrating the Barometric Sensor (Rapid Lab 1200 instruments) when the laboratory processed and reported 15,533 blood gases patients samples from January 1, 2018 to August 14, 2019. The findings include: 1. The manufacturer's instruction establishes that the laboratory check the barometer calibration every day of testing. 2. From January 1, 2018 to August 14, 2019, the blood gases quality control records showed that the laboratory did not perform nor document the barometer calibration every day of testing. 3. The laboratory processed and reported 15,533 blood gases samples patient's tests from January 1, 2018 to August 14, 2019. 4. The testing personnel stated on August 14, 2019 at 11:26 AM, that the laboratory did not performed nor document the barometer calibration every day of testing since January 1, 2018.
D5479	CONTROL PROCEDURES CFR(s): 493.1256(e)(5)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (5) Follow the manufacturer's specifications for using reagents, media, and supplies and be responsible for results. (g) The laboratory must document all control procedures performed.

	This STANDARD is not met as evidenced by: Based on body fluid cells count testing records, cell-check manufacturer instructions review and laboratory general supervisor interview on August 14, 2019 at 11:55 AM, it was determined that the laboratory failed to follow the manufacturer's specifications for using the body fluid cells count controls materials when 5 out of 5 body fluid patients specimens were count and reported from June 6, 2019 to August 6, 2019. The findings include: 1. The laboratory performed the body fluid cells count by hemacytometer. 2. The laboratory used the cell-check control materials. 3. The cell-check manufacturer instructed the laboratory to use the control materials with 30 consecutive days open-vial stability (OVS). 4. On August 14, 2019 at 11:55 AM, the body fluid cells count testing records showed that the laboratory have in used one vial of the cell-check control material (lot 90980412; open on April 22, 2019). The used this vial of control material with the OVS exceed from June 6, 2019 to August 6, 2019. 6. The laboratory general supervisor confirmed on August 14, 2019 at 11:55 AM, that the laboratory used this control material vial with the OVS exceed from June 6, 2019 to August 6, 2019. 7. The laboratory processed and reported 5 out of 5 body fluid patients specimens were count and reported from June 6, 2019 to August 6, 2019: patients specimens H00048R, patients specimens H000563, patients specimens H33287, patients specimens H339134 and patients specimens H143815.
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(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, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 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 blood bank (BB) policies records, BB quality assessment records (years 2018-2019), BB blood component utilization records (2019) and interview with the general supervisor on August 14, 2019 at 10:30 AM, it was determined that the BB director failed to ensure that the transfusion reactions were promptly identify since April 11, 2017. Refer to D 3025.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control 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 blood bank (BB) procedures manuals review, Rapid Lab 1200 manufacturer's instruction , blood gases quality control records, cell-check manufacturer instructions, body fluid cells count testing records review, testing personnel and laboratory general supervisor interview on August 14, 2019 at 11:55 AM, it was determined that the laboratory director failed to ensure compliance with the requirements for the analytic system. Refer to D 5401 (The BB failed to have a written procedure to ensure that the temperature of the blood unit was maintained if the blood unit is returned to the blood bank since January 2019). Refer to D 5405 (The laboratory failed to follow the manufacturer's instruction for calibrating the Barometric Sensor (Rapid Lab 1200 instruments) when the laboratory processed and reported 15,533 blood gases patients samples from January 1, 2018 to August 14, 2019). Refer to D 5479 (The laboratory failed to follow the manufacturer's specifications for using the body fluid cells count controls materials when 5 out of 5 body fluid patients specimens were count and reported from June 6, 2019 to August 6, 2019).
D6144	GENERAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1463 The general supervisor is responsible for day-to-day supervision or oversight of the laboratory operation and personnel performing testing and reporting test results. This STANDARD is not met as evidenced by: Based on blood bank (BB) procedures manuals review, Rapid Lab 1200 manufacturer's instruction , blood gases quality control records, cell-check manufacturer instructions, body fluid cells count testing records review, testing personnel and laboratory general supervisor interview on August 14, 2019 at 11:55 AM, it was determined that the the general supervisor failed to perform day-to-day supervision for the personnel that performing testing and reporting test results. Refer to D 5405 (The laboratory failed to follow the manufacturer's instruction for calibrating the Barometric Sensor (Rapid Lab 1200 instruments) when the laboratory processed and reported 15,533 blood gases patients samples from January 1, 2018 to August 14, 2019). Refer to D 5479 (The laboratory failed to follow the manufacturer's specifications for using the body fluid cells count controls materials when 5 out of 5 body fluid patients specimens were count and reported from June 6, 2019 to August 6, 2019).
D6177	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1495(b)(3) Each individual performing high complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed. This STANDARD is not met as evidenced by: Based on blood bank (BB) procedures manuals review, Rapid Lab 1200 manufacturer's instruction , blood gases quality control records, cell-check manufacturer instructions, body fluid cells count testing records review, testing personnel and laboratory general supervisor interview on August 14, 2019 at 11:55 AM, it was determined that the testing personnel failed to follow quality control procedures. Refer to D 5405 (The laboratory failed to follow the manufacturer's

	instruction for calibrating the Barometric Sensor (Rapid Lab 1200 instruments) when the laboratory processed and reported 15,533 blood gases patients samples from January 1, 2018 to August 14, 2019). Refer to D 5479 (The laboratory failed to follow the manufacturer's specifications for using the body fluid cells count controls materials when 5 out of 5 body fluid patients specimens were count and reported from June 6, 2019 to August 6, 2019).