Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0000464	04/04/2019
Name of Provider or Supplier	**Street Address, City, State**	
Lab Clinico Ryder Memorial Hospital	355 Ave Font Martelo, Humacao, 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
D5024	HEMATOLOGY CFR(s): 493.1215 If the laboratory provides services in the specialty of Hematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1269, and 493. 1281 through 493.1299. This CONDITION is not met as evidenced by: Based on prothrombin time (PT) quality control records (years 2017, 2018 and 2019), normal patient PT calculate mean records (years 2017 and 2018), Hemosil PT Fibrinogen #5 plus manufacturer's instructions, quality control records (years 2017, 2018 and 2019) for prothrombin time (PT) and Partial Thromboplastin Time (PTT) test and interview with the laboratory director on April 4, 2019 at 11:10 AM, it was determined that the laboratory failed to meet the analytic system requirements for Hematology specialty (PT and PTT tests). Refer to D 5545 (1) (2).
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on personnel records review, laboratory director and general supervisor interview on April 4, 2019 at 2:11 PM, it was determined that the laboratory failed to follow the established schedule for the testing personnel competence since January 2018. The findings include: 1. The laboratory schedule for testing personnel competence evaluation showed that the laboratory must be performed every year the

	testing personnel competence. 2. The testing records were reviewed since January 2017. 3. The technical supervisor did not perform the testing personnel (MT # 16) competence evaluation since January 2018. 4. This deficiency was cited on April 12, 2017 survey.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on Quality Assessment (QA) records review(years 2017, 2018 and 2019), laboratory director and general supervisor interview on April 4, 2019 at 2:11 PM, it was determined that the laboratory failed to follow the established Quality assessment Program to monitor and evaluate the requirements for general laboratory systems (personnel competence). The findings include: 1. The laboratory QA records, showed that the testing personnel competence must be performed every year. 2. The laboratory did not evaluate the testing personnel (MT # 16) competence since January 2018. 3. This deficiency was cited on April 12, 2017 survey.
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 Rapidlab system operator's guide: maintenance instructions, atmospheric barometric pressure records (years 2018 and 2019) for Rapidlab system # 16844 and Rapidlab system # 16767 and interview with the general supervisor on April 4, 2019 at 2:00 PM, it was determined that the laboratory failed to follow manufacturer's instruction to check every day the barometer calibration of the Rapidlab system # 16844 in 150 out of 365 days and for the Rapidlab system # 16767 in 147 out of 365 days during the year 2018. The findings include: 1. The laboratory performed the patients blood gases specimens by two Rapidlab system (Rapidlab system # 16844 and Rapidlab system # 16767). 2. The Rapidlab system operator's guide: maintenance instructed the laboratory to check the barometer calibration every day. 3. On April 4, 2019 at 2:00 PM, the Rapidlab system atmospheric barometric pressure records showed that the laboratory did not to check every day the barometer calibration of the two Rapidlab systems during the year 2018: a . The laboratory did not check the barometer calibration of the Rapidlab system # 16844 in 150 out of 365 days during the year 2018. b. The laboratory did not check the barometer calibration of the Rapidlab system # 16767 in 147 out of 365 days during the year 2018. 4. The general supervisor stated on April 4, 2019 at 2:00 PM, that the the barometer calibration in

	both systems were checked but not recorded those days. 5. The laboratory processed and reported 3, 242 patients blood gases by the Rapidlab systems during the year 2018.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on written procedures, blood gases room temperature record (years 2018 and 2019), blood gases room humidity record (years 2018 and 2019) review and interview with the general supervisor on April 4, 2019 at 12:40 PM, it was determined that the laboratory failed to follow written procedures to monitor and document the room temperature and the humidity where 3, 242 out of 3,242 patients blood gases were processed and reported by the the two Rapidlab systems from January 1, 2018 to December 31, 2018. The findings include: 1. The laboratory processed and reported the patients blood gases specimens by two Rapidlab systems aisle in a room at the end of the work flow in the laboratory. 2. The written procedures establish the following range of room temperature and humidity required conditions for the proper function of the two Rapidlab systems: room temperature range form 65 F to to 75 F and room humidity range from 20 % to 80 %. 3. On April 4, 2019 at 12:40 PM, the blood gases temperature record showed that the laboratory did not monitor nor document the room temperature in 143 out of 365 days from January 1, 2018 to December 31, 2018. Also, this records showed that the laboratory documented temperatures out of acceptable range in 13 out of 365 days from January 1, 2018 to December 31, 2018. 4. On April 4, 2019 at 12:40 PM, the blood gases humidity record showed that the laboratory did not monitor nor document the room humidity in 162 out of 365 days from January 1, 2018 to December 31, 2018. 5. The general supervisor confirmed on April 4, 2019 at 12:40 PM, that the laboratory did not monitor nor document the room temperature nor the room humidity those days. 6. The laboratory processed and reported 3, 242 out of 3,242 patients blood gases by the the two Rapidlab systems from January 1, 2018 to December 31, 2018.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on Rapidlab system manufacturer instructions, Rapidlab system (#16767) preventive maintenance records (years 2018 and 2019) and interview with the general superviosr on April 4, 2019 at 11:05 am, it was determined that the laboratory did not

	follow manufacture's instruction for the preventive maintenance of the Rapidlab system (#16767) from January 1, 2018 to December 31, 2018. The findings include: 1. The laboratory processed and reported the blood gasses patients specimens by the Rapidlab system. 2. The Rapidlab manufacturer requires a daily, weekly and quarterly preventive maintenance for the proper function of the Rapidlab system. 3. On April 4, 2019 at 11:05 am, Rapidlab system (#16767) preventive maintenance records showed that the laboratory did not perform the following required preventive maintenance: a. The laboratory did not perform the quarterly preventive maintenance from January 1, 2018 to December 31, 2018. b. The laboratory did not perform the weekly preventive maintenance in the following months: 2 out of 2 weeks in February 2018, 3 out of 4 weeks in April 2018, 2 out of 4 weeks in May 2018, 3 out of 4 weeks in June 2018, 3 out of 4 weeks in September 2018, 4 out of 4 in August 2018, 2 out of 4 in October 2018 and 3 out of 4 in November 2018. c. The laboratory did not perform the daily preventive maintenance in the following months: 29 out of 31 days in October 2018; 28 out of 30 days in November 2018 and 28 out of 31 days in December 2018. 4. The general superviosr stated on April 4, 2019 at 11:05 am, that the preventive maintenance were performed but not records. 5. The laboratory processed and reported 3, 242 out of 3,242 patients blood gases by the the two Rapidlab systems from January 1, 2018 to December 31, 2018.
D5545	HEMATOLOGY CFR(s): 493.1269(b)(d) (b) For all nonmanual coagulation test systems, the laboratory must include two levels of control material each 8 hours of operation and each time a reagent is changed. (d) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: 1. Based on prothrombin time (PT) quality control records (years 2017, 2018 and 2019), normal patient PT calculate mean records (years 2017 and 2018), Hemosil PT Fibrinogen #5 plus manufacturer's instructions review and interview with the laboratory director on April 4, 2019 at 11:10 AM, it was determined that the laboratory did not incorporate the pertinent normal patient PT mean when it calculated and reported 2,297 out of 2,297 patient's INR (International Normalized ratio) results from February 1, 2018 to October 10, 2018. The findings include: a. The laboratory used the Hemosil PT Fibrinogen #5 plus reagent for to process the PT tests and to calculated and reports the patient's INR results. b. The Hemosil PT Fibrinogen #5 plus manufacturer instructed the laboratory to calculate a normal patient PT mean for every new reagent lot to calculate and report the patient's INR results. c. On April 4, 2019 at 11:20 AM, the normal patient PT calculate mean records showed that the laboratory placed the new lot of Hemosil PT Fibrinogen #5 plus (lot# N0184832) on February 1, 2018. The laboratory did not calculate the normal patient PT mean for this new lot of reagent. However, the laboratory used the normal patient PT mean (13.9 seconds) of the former Hemosil PT Fibrinogen #5 plus reagent (lot N0562716) to calculate and report the patient's INR results from February 1, 2018 to October 10, 2018. d. The laboratory director on April 4, 2019 at 11:10 AM, confirmed that the laboratory did not calculate the normal patient PT mean for this new lot of reagent (lot# N0184832) and confirmed that the laboratory used the former PT mean of 13.9 second to calculate the patient's INR results from February 1, 2018 to October 10, 2018 . e. The laboratory calculated and reported 2,297 out of 2,297 patient's INR results from February 1, 2018 to October 10, 2018. 2. Based on quality control records (years

	2017, 2018 and 2019) for prothrombin time (PT) and Partial Thromboplastin Time (PTT) test and interview with the laboratory director on April 4, 2019 at 10:30 AM, it was determined that the laboratory failed to include two levels of control material each 8 hours of operation when 10,632 out of 10.632 PT and PTT patients specimens were processed and reported form September 25, 2017 to April 3, 2019. The findings include: a. On April 4, 2019 at 10:30 AM, the quality control records for PT and PTT tests showed that the laboratory included two levels of control material for Pt and PTT tests each 12 hours of operation form September 25, 2017 to April 3, 2019. b. The laboratory director confirmed on April 4, 2019 at 10:30 AM, that the laboratory included the two levels of control material each 12 hours of operation form September 25, 2017 to April 3, 2019. She stated that this practice was established since the Hurricane Maria. c. The laboratory processed and reported 10,632 out of 10.632 PT and PTT patients specimens form September 25, 2017 to April 3, 2019.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on routine chemistry quality control records (years 2017, 2018 and 2019) review and laboratory director and routine chemistry testing personnel interview on April 4, 2019 at 11:43 AM, it was determined that the laboratory failed to evaluate twice a year the relationship between the routine chemistry tests process by the Dimension EXL 200 and by the Dimension EXLM systems. The findings includes: 1. The laboratory uses a Dimension EXL 200 and Dimension EXLM systems to perform the routine chemistry patients samples tests. 2. Review of the routine chemistry quality control records (years 2017, 2018 and 2019), showed that the laboratory did not evaluate twice a year the relationship between the routine chemistry tests results processed by the Dimension EXL 200 and Dimension EXLM systems since March 2017. 3. The laboratory evaluated annually the relationship between the routine chemistry tests results processed by the Dimension EXL 200 and by the Dimension EXLM systems in March 2017 and October 2018. 4. The laboratory director and the routine chemistry testing personnel confirmed on April 4, 2019 at 11:43 AM, that the laboratory did not evaluate twice a year the relationship of those results. 5. The laboratory annual volumes records showed that the laboratory processed 234,879 out of 234,879 routine chemistry tests. 6. This deficiency was cited on April 12, 2017 survey.
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s).

	This STANDARD is not met as evidenced by: Based on investigation of transfusion reactions worksheet records review from January 2018 to March 2019 and laboratory director and blood bank testing personnel interview on April 4, 2019 at 1:23 PM, it was determined that the laboratory failed to ensure that the laboratory did not use of whiteout in the transfusion reactions worksheet. The findings includes: 1. Review of the transfusion reactions worksheet from January 2018 to March 2019, showed that the laboratory uses the whiteout in 18 out of 30 transfusion reactions worksheet. 2. The laboratory director and blood bank testing personnel confirmed on April 4, 2019 at 1:23 PM, that the laboratory uses whiteout in those worksheet.
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 prothrombin time (PT) quality control records (years 2017, 2018 and 2019), normal patient PT calculate mean records (years 2017 and 2018), Hemosil PT Fibrinogen #5 plus manufacturer's instructions, quality control records (years 2017, 2018 and 2019) for prothrombin time (PT) and Partial Thromboplastin Time (PTT) test, Rapidlab system operator's guide: maintenance instructions, atmospheric barometric pressure records (year 2018) for Rapidlab system # 16844 and Rapidlab system # 16767, written procedures, blood gases room temperature record (year 2018), blood gases room humidity record (2018), Rapidlab system (#16767) preventive maintenance records (years 2018 and 2019),routine chemistry quality control records, blood transfusion records, QA records, personnel file records review and interview with laboratory director the general superviosr on April 4, 2019 at 2:00 PM, it was determined that the laboratory director failed to fulfill her responsibilities and duties to ensure compliance with the laboratory analytical system and quality assessment requirements. The findings include: 1. The laboratory director did not comply with the analytical systems requirements. Refer to D 6093. 2. The laboratory director did not comply with the quality assessment requirements. Refer to D 6094. 3. The laboratory director did not ensure that prior to testing patients' specimens, all personnel have the appropriate training. Refer to D 6102.
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 prothrombin time (PT) quality control records (years 2017, 2018 and 2019), normal patient PT calculate mean records (years 2017 and 2018), Hemosil PT Fibrinogen #5 plus manufacturer's instructions, quality control records (years 2017,

	2018 and 2019) for prothrombin time (PT) and Partial Thromboplastin Time (PTT) test, Rapidlab system operator's guide: maintenance instructions, atmospheric barometric pressure records (year 2018) for Rapidlab system # 16844 and Rapidlab system # 16767, written procedures, blood gases room temperature record (year 2018), blood gases room humidity record (2018), Rapidlab system (#16767) preventive maintenance records (years 2018 and 2019),routine chemistry quality control records, blood transfusion records and interview with laboratory director the general superviosr on April 4, 2019 at 2:00 PM, it was determined that laboratory director failed to comply with the requirements for analytic systems. The findings include: 1. Refer to D 5024 (The laboratory failed to meet the analytic system requirements for Hematology specialty for the PT and PTT tests). 2. Refer to D 5405 (The the laboratory failed to follow manufacturer's instruction to check every day the barometer calibration of the Rapidlab system # 16844 in 150 out of 365 days and for the Rapidlab system # 16767 in 147 out of 365 days during the year 2018). 3. Refer to D 5413 (The laboratory failed to follow written procedures to monitor and document the room temperature and the humidity where 3, 242 out of 3,242 patients blood gases were processed and reported by the the two Rapidlab systems from January 1, 2018 to December 31, 2018). 4. REfer to D 5429 (The laboratory did not follow manufacture's instruction for the preventive maintenance of the Rapidlab system (#16767) from January 1, 2018 to December 31, 2018). 5. Refer to D 5775 (The laboratory failed to evaluate twice a year the relationship between the routine chemistry tests systems). 6. Refer to D 5787 (The laboratory failed to ensure that the laboratory did not use the whiteout in the transfusion reaction worksheet).
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 Quality Assessment (QA) records review, laboratory director and general supervisor interview on April 4, 2019 at 1:48 PM, it was determined that laboratory director failed to ensure compliance with QA requirements. The finding includes: 1. Refer to D 5291 (The laboratory did not evaluate the requirements for general laboratory systems).
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on personnel file records review and general supervisor interview on April 4, 2019 at 1:40 PM, it was determined that the laboratory director failed to ensure that two new testing personnel of blood gases tests have the appropriate training prior to

	testing patients' specimens for blood gases patients tests. The findings include: 1. The laboratory hired two testing personnel for blood gases (one on march 2019 and the other on August 2018). 2. On April 4, 2019 at 1:40 PM, the personnel file of this two testing personnel did not include the complete training for the processing of the blood gases patients specimens by the Rapidlab systems. 3. Refer to D 5405. (The laboratory failed to follow manufacturer's instruction to check every day the barometer calibration of the Rapidlab system # 16844 in 150 out of 365 days and for the Rapidlab system # 16767 in 147 out of 365 days during the year 2018). 4. Refer to D 5413 (The laboratory failed to follow written procedures to monitor and document the room temperature and the humidity where 3, 242 out of 3,242 patients blood gases were processed and reported by the the two Rapidlab systems from January 1, 2018 to December 31, 2018). 5. Refer to D 5429 (The laboratory did not follow manufacture's instruction for the preventive maintenance of the Rapidlab system (#16767) from January 1, 2018 to December 31, 2018).
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by: Based on testing personnel records review and laboratory director and general supervisor interview on April 4, 2019 at 2:11 PM, it was determined that the technical supervisor failed to provide the competence evaluation and training to the testing personnel that performed the high complexity tests since January 2018. The findings include: 1. Review of personnel records, showed that the technical supervisor failed to evaluate the annual competency of the testing personnel (MT # 16) that that include at least the following requirements since January 2018: a. Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. b. Monitoring, recording and reporting of test results. c. Review of intermediate test results or worksheets, quality control records, proficiency testing results and preventive maintenance records. d. Direct observation of performance of instrument maintenance and function checks. e. Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. 2. This deficiency was cited on April 12, 2017 survey.
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 prothrombin time (PT) quality control records (years 2017, 2018 and 2019), normal patient PT calculate mean records (years 2017 and 2018), Hemosil PT Fibrinogen #5 plus manufacturer's instructions, quality control records (years 2017,

	2018 and 2019) for prothrombin time (PT) and Partial Thromboplastin Time (PTT) test, Rapidlab system operator's guide: maintenance instructions, atmospheric barometric pressure records (year 2018) for Rapidlab system # 16844 and Rapidlab system # 16767, written procedures, blood gases room temperature record (year 2018), blood gases room humidity record (2018), Rapidlab system (#16767) preventive maintenance records (years 2018 and 2019), routine chemistry quality control record and interview with the general superviosr on April 4, 2019 at 2:00 PM, perform day-to-day supervision for the personnel that performing testing and reporting test results. Refer to D 5545 (1)(2). Refer to D 5405. Refer to D 5413. Refer to D 5429. Refer to D 5775.
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 prothrombin time (PT) quality control records (years 2017, 2018 and 2019), normal patient PT calculate mean records (years 2017 and 2018), Hemosil PT Fibrinogen #5 plus manufacturer's instructions, quality control records (years 2017, 2018 and 2019) for prothrombin time (PT) and Partial Thromboplastin Time (PTT) test, Rapidlab system operator's guide: maintenance instructions, atmospheric barometric pressure records (year 2018) for Rapidlab system # 16844 and Rapidlab system # 16767, written procedures, blood gases room temperature record (year 2018), blood gases room humidity record (2018), Rapidlab system (#16767) preventive maintenance records (years 2018 and 2019), routine chemistry quality control records and interview with the general superviosr on April 4, 2019 at 2:00 PM, it was determined that testing personnel failed to follow quality control procedures. Refer to D 5545 (1)(2). Refer to D 5405. Refer to D 5413. Refer to D 5429. Refer to D 5775.