Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0658280	04/10/2018
Name of Provider or Supplier	**Street Address, City, State**	
Pavia Hato Rey Hospital Lab	435 Ponce De Leon Avenue, Hato Rey, 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
D2094	ROUTINE CHEMISTRY CFR(s): 493.841(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on Puerto Rico Proficiency Testing (PT) Program (year 2016 and 2017) records review and laboratory director interview on April 10, 2018 at 4:00 PM, it was determined that the laboratory failed to take and document remedial action when it obtained unacceptable analyte score of routine chemistry proficiency testing results in the first testing PT event (February 2017). The findings include: 1. The laboratory did not take nor document remedial action when it obtained unacceptable analyte score of proficiency testing results for total bilirubin (80 %) and for lactate dehydrogenase (80 %) proficiency testing results in the first PT event (February 2017). 2. The laboratory director confirmed on April 10, 2018 at 4:00 PM, that no remedial actions were taken nor documented during the year 2017.
D2116	TOXICOLOGY CFR(s): 493.845(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score,

	remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on Puerto Rico Proficiency Testing Program (year 2016 and 2017) records review and laboratory director interview on April 10, 2018 at 4:00 PM, it was determined that the laboratory failed to take and document remedial action when it obtained unacceptable analyte score of toxicology proficiency testing results in the first testing event (February 2017). The findings include: 1. The laboratory did not take nor document remedial action when it obtained unacceptable analyte score of proficiency testing results for valproic acid (80 %) proficiency testing results in the first PT event (February 2017). 2. The laboratory director confirmed on April 10, 2018 at 4:00 PM, that no remedial actions were taken nor documented during the year 2017.
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 patient's transfusion records review and interview with the laboratory director on April 10, 2018 at 3: 20 PM , it was found that the laboratory did not follow written instructions for evaluation of possible transfusion reactions. The findings include: a. The laboratory director was interviewed about the procedures for possible transfusion reactions detection and further evaluation. She stated that the nursing personnel in charge of the patient must be aware of any sign or symptom during and after the transfusion. If they notice any alteration they must call the laboratory, then the laboratory will start with the evaluation of the possible reaction. Regarding patient temperature requirement she stated during ionterview and the written instruction showed that any change within 1C of the initial patient temperature must be considered a possible transfusion reaction. b. Three patient's transfusion records were evaluated with the following findings: i. Patient identification 261739- Unit transfused on April 3, 2018: W236518370079. The record showed a change in patient temperature from 36.9 C to 39.4C. The possible transfusion reaction was not evaluated. ii. Patient identification 261739- Unit transfused on April 5, 2018: W236518072703 (fractioned unit) . The record showed a change in patient temperature from 36.2 C to 37.3C. The possible transfusion reaction was not evaluated. iii. Patient identification 186/186- Unit transfused on April 9, 2018: W036818052124. The record showed a change in patient temperature from 36.2 C to 37.5C. The possible transfusion reaction was not evaluated.
D5014	GENERAL IMMUNOLOGY CFR(s): 493.1208 If the laboratory provides services in the subspecialty of General immunology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, and

	493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on Alere Determined HIV-1/2 Ag/Ab Combo performance specification procedures, quality control records patient records review and interview with the laboratory director and the MT's 7 and 8 on April 10, 2108 at 2:00 PM, it was determined that the laboratory failed to meet the requirements in the subspecialty of General Immunology for HIV tests. Refer to : D5421- the verification of performance specification was performed by the manufacturer company specialist. D5449- The laboratory did not include positive and negative control material D5401- The laboratory did not follow written instruction for patient rerun.
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 direct observation, R & B body fluid hematology control manufacturer's instructions, Hematology procedures manual, body fluid testing and quality control records, R & B body fluid hematology control Kit insert records, hematology quality control records, platelets quality control graphs records, coagulation procedures manual, Prothrombin Time (PT) quality control records (years 2017 and 2018), International Normalized Ration (INR) values results records review, laboratory director and testing personnel (Medical Technologist #3) interview on April 10, 2018 at 3:20 PM, it was determined that the laboratory failed to meet the analytic requirements in the specialty of Hematology. Refer to D 5405 (The laboratory failed to follow quality control procedures when 8 out of 8 body fluid patients' specimens were processed for cells count by the hemocytometer from October 19, 2017 to April 4, 2018). Refer to D 5481 (The laboratory failed to take and document corrective actions for platelets quality control graphs trend when 1,234 out of 1,234 complete blood cell (CBC) patients' specimens were processed and reported by the Coulter LH 780 system from January 17, 2018 to January 31, 2018). Refer to D 5545(1) (The laboratory failed to include two levels of control each 8 hours of operation for PT tests by the CA1500 system in May 13, 2017 and January 27, 2018). Refer to D 5545(2) (The laboratory failed to have a written procedure to determine and calculate the INR tests nor the PT mean population value, since May 2017).
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: 1. Based on review of the laboratory written instructions for the Alere Determine HIV-

	1/2 Ag/Ab Combo test, HIV patient's logbook and interview with the MT # 8 on April 10, 2018 at 2:20 PM, it was found that the laboratory did not follow the written procedure regarding the rerun of patient samples showing initially reactive test results to HIV antigen (Ag) or antibody (Ab). The findings include: a. Since November 17, 2017 the laboratory processed HIV patient's samples by the Alere Determine HIV-1/2 Ag/Ab Combo. b. The laboratory written instructions showed the following" " Positive results for Ag or Ab, must be repeated and both runs must be documented in the logbook; copy of the printed test results must be kept at the end of the logbook". c. Review of the patient's test logbook showed that on March 6, 2018 patient # 659908 had a preliminary positive test result for Ag/Ab. The patient sample was not repeated. d. Review of the patient's test logbook showed that on March 7, 2018 patient # 6660376 had a preliminary positive test result for Ag/Ab. The patient sample was not repeated. e. The MT #7 stated during interview that as established in the written instructions, the sample must be repeated before being reported. 2. Based on review of the Alere Determine HIV-1/2 Ag/Ab Combo test manufacturer's instructions (Rev. 6 -2013/11) , lack of room temperature records and interview with the MT's 7 and 8, it was found that the laboratory did not follow the written instructions about the laboratory room temperature before performing the test. The findings include: a. The manufacturer instructed the laboratory to perform the test at a temperature range of 15 to 30 C (59 -86 F). b. The room temperature records, at the time of patient's samples testing, was requested to the testing personnel. c. The testing personnel stated that they did not have the room temperature records at the time of testing. That they had a digital thermometer on the wall but they did not have documentation of it. d. Since November 17, 2017 to April 8, 2018 the laboratory processed 46 patient's samples in 41 days.
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 direct observation, R & B body fluid hematology control systems manufacturer's instructions, Hematology procedures manual, body fluid testing and quality control records, R & B body fluid hematology control Kit insert records review and testing personnel (Medical Technologist #3) interview on April 10, 2018 at 10:05 AM, it was determined that the laboratory failed to follow quality control procedures when 8 out of 8 body fluid patients specimens were processed for cells count by the hemocytometer from October 19, 2017 to April 4, 2018. The findings include: 1. The body fluid testing records showed that the laboratory processed patient's specimens body fluid cells counts by hemocytometer since April 10, 2016. 2. The body fluid quality control records showed that the laboratory used the R & B body fluid hematology controls material since October 19, 2017. 3. It was observed on April 10, 2018 at 10:05 AM, that the 4 out of 4 R & B body fluid control material vials Lot BF 0318 in use (stored in the hematology refrigerator) did not include the opened date. This lot kit was received on February 21, 2018. 4. The procedures manual establishes that the body fluid hematology control material are stable for 30 day opened vials. 5. The insert of the R & B body fluid controls material in use, instructed the laboratory that the unopened vials are stable through the expiration date

	and the opened vials are stable 90 days or 31 thermal cycles (uses) whichever comes first, provided they are handled property. 6. The body fluid quality control records showed that the laboratory used the R & B body fluid hematology control materials with exceeded stability date when 8 out of 8 body fluid patients' specimens were processed for cells count by the hemocytometer from October 19, 2017 to April 4, 2018: Date Body fluid control level lot/exp date October 19, 2017 level 1, lot BF 0917-1/2017-09-05 October 19, 2017 level 2, lot BF 0917-2/2017-09-05 October 21, 2017 level 1, lot BF 0917-1/2017-09-05 October 21, 2017 level 2, lot BF 0917-2/2017-09-05 October 26, 2017 level 1, lot BF 0917-1/2017-09-05 October 26, 2017 level 2, lot BF 0917-2/2017-09-05 November 20, 2017 level 1, lot BF 0917-1/2017-09-05 November 20, 2017 level 2, lot BF 0917-2/2017-09-05 November 24, 2017 level 1, lot BF 0917-1/2017-09-05 November 24, 2017 level 2, lot BF 0917-2/2017-09-05 September 19, 2017 level 1, lot BF 0917-1/2017-09-05 September 19, 2017 level 2, lot BF 0917-2/2017-09-05 March 11, 2018 level 2, lot BF 0318-2/2018-03-05 April 4, 2018 level 2, lot BF 0318-2/2018-03-05 7. The testing personnel (Medical Technologist #3) confirmed on April 10, 2018 at 10:15 AM that the body fluid quality control records showed that the laboratory used the R & B body fluid hematology control materials with exceeded stability date when 8 out of 8 body fluid patients' specimens were processed for cells count by the hemocytometer from October 19, 2017 to April 4, 2018. She also stated, that was a laboratory clerical error in the documentation of the body fluid quality control record.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of the Alere HIV-1/2 Ag/Ab Combo verification of performance specification work sheet and interview with the Medical Technologists (MT's) 7 and 8 on April 10, 2018 at 2:00 PM, it was determined that the laboratory personnel did not verify the Alere HIV-1/2 Ag/Ab Combo test performance. The findings include: a. Review of the Alere HIV-1/2 Ag/Ab Combo verification of performance specification work sheet dated on August 30, 2017, showed that the correlation was performed and signed by the manufacturer specialist. b. The records did not include information about the known samples used, also did not identify by which method the samples were initially tested. c. The MT's 7 and 8 state that the manufacturer specialist was the one who performed the testing procedure on August 30, 2017 and the laboratory testing personnel did not participate, directly in the process. c. The procedure was not verified or signed by the laboratory director or any other personnel.
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 review of Vitros 5600 manufacturer's instructions, instrument preventive maintenance records review and interview with the testing personnel (Medical Technologist -MT 7 and MT 8) on April 10, 2018 at 10:30 am, it was found that the laboratory did not perform the established daily nor monthly preventive maintenance as required by the manufacturer. The findings include: a. The manufacturer instructed the laboratory to perform the following daily preventive maintenance: Maintain ERF, Maintain IWF (72 hours), Perform Metering Maintenance, Empty Waste Container, Load Supplies and Remove Empty/Outdated Reagents, Inspect/Clean Universal Sample Trays and Adaptors, Clean SR Dispense Probe, Clean Cap retainers, Clean VersaTip Supply Registration Rails, Clean uWell Wash Probes (both Arms) and Clean Primary Tip Sealer. b. Review of the Vitros 5600 daily preventive maintenance records from December 1, 2016 to March 31, 2018 showed that in one hundred twenty one out of four hundred- eighty six days of use (121 out 486) the laboratory did not complete the required preventive maintenance. c. The manufacturer instructed the laboratory to perform the following monthly preventive maintenance: Clean Cuvette Arm, Clean Cuvette Incubator, Clean PM Discard Chute, Clean/Replace PM Evaporation Caps, Clean PM Incubator Slot and Insert Blade Channels, Clean MicroSensor Cover and Ring Area, Inspect/Clean uIA Reagent Supply Top Cover, Inspect/Clean Supply 3 Pack Opener, Clean VersaTip Supply and Inspect/Clean Reagent Cooler filter, d. Review of the Vitros 5600 monthly preventive maintenance documents from December 2016 to March 2018 showed that the laboratory did not perform the maintenance in January 2017, February 2017, March 2017, April 2017, July 2017, August 2017, September 2017, November 2017, February 2018 nor March 2018. e. The MT's 7 and 8 stated during interview that failures in preventive maintenance were mostly with the per diem testing personnel during the weekends. f. The laboratory processed 93,010 patient's samples from January 2017 to April 9, 2018.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent

	calibration verification. This STANDARD is not met as evidenced by: Based on review of Vitros 5600 verification performance specifications, Vitros 5600 established reportable range, calibration verification records review and interview with testing personnel 7 and 8 on April 10, 2018 at 11:00 am, it was found that the laboratory did not perform calibration verification procedures for direct Total Iron Binding Capacity (dTIBC). The findings include: a. The laboratory performed the dTIBC test by the Vitros 5600 system. b. The calibration verification records reviewed , since year 2015, did not include any procedure for dTIBC. c. Review of the Vitros 5600 verification performance specifications, showed that the initial verification was performed on December 4, 2014. d. During interview with testing personnel 7 and 8 on April 10, 2018 at 11:00 AM they stated that the laboratory never performed calibration verification procedures for dTIBC. e. The observed established reportable range on the Vitros 5600 instruments was from 60 -650 ng/dl. f. The last reportable range established by the laboratory was from 60 - 316 ug/dl. g. From January 2016 to April 9, 2018 the laboratory processed and reported two hundred fifty-seven (257) dTIBC patient samples. h. Review at random of twenty four (24) dTIBC patient test reports from January 17, 2017 to March 30, 2018 showed that fourteen of them showed reported dTIBC results over the upper established limit of 316 ug/dl.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of Alere Determine Human Immunodeficiency Virus (HIV) -1/2 Ag /Ab Combo quality control and patient's logbook records and interview with the laboratory director and MT's 7 and 8 on April 10, 2018 at 2:20 PM, it was found that the laboratory did not include a negative and a positive quality control material each day of patient testing. The findings include: a. The laboratory used the Alere Determine HIV-1/2 Ag/Ab Combo to perform serum HIV patient's test. b. During the entrance conference the laboratory director stated that they implemented the Individual Quality Control Plan (IQCP) for the HIV tests performed by the Alere Determine HIV-1/2 Ag/Ab Combo. c. The laboratory director stated that the established quality control plan (QCP) was to run the control material with each new lot and every first and third Monday of each month. d. On April 10, 2018 at 2:20 PM the HIV - IQCP was requested for evaluation. The MT # 8 showed a page with ten (10) positive and negative control results, as the HIV Quality Control Plan (QCP) e. The laboratory director then stated that she was collecting information for the HIV IQCP, however she did not prepare a IQCP for the HIV test. The laboratory director stated that she was the one who decided the frequency of the control material runs. f. As shown in the quality control log book the established frequency was less than the CLIA regulation for qualitative tests. g. Review of the quality control and patient's logbook records showed that from November 17, 2017 to April 8, 2018 the laboratory processed 46 patient's samples in 41 days. The laboratory included a positive and a

	negative control material only on December 4, 2017, when two patient's samples were processed.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on hematology quality control records, platelets quality control graphs records review and testing personnel (Medical Technologist #3) interview on April 10, 2018 at 11:10 AM, it was determined that the laboratory failed to take and document corrective actions for platelets quality control graphs trend when 1,234 out of 1,234 complete blood cell (CBC) patients specimens were processed and reported by the Coulter LH 780 system from January 17, 2018 to January 31, 2018 The findings include: 1. The hematology quality control records showed that the laboratory processed and reported the CBC patient's specimens by the Coulter LH 780 system. 2. On April 10, 2018 at 11:10 AM, the platelets quality control graphs showed trends in the 3 out 3 levels of the CBC hematology control materials from January 17, 2018 to January 31, 2018. 3. The hematology quality control records did not include any corrective action taken nor documented for the trend analysis in order to determine if it was clinically relevant for the patients specimens from January 17, 2018 to January 31, 2018. 4. The laboratory processed and reported 1,234 out of 1,234 CBC patients specimens by the Coulter LH 780 system from January 17, 2018 to January 31, 2018 5. The testing personnel (Medical Technologist #3) confirmed on April 10, 2018 at 11: 10 AM, that the laboratory did not take nor documented corrective action for the platelets quality control trend from January 17, 2018 to January 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 observation, coagulation procedures manual, Prothrombin Time (PT) quality control records (years 2017 and 2018) review, laboratory director and testing personnel (Medical Technologist #3) interview on April 10, 2018 at 3:00 PM, it was determined that the laboratory failed to include two levels of control each 8 hours of operation for PT tests porcessed by the CA1500 system in May 13, 2017 and in January 27, 2018. The findings include: a. The PT quality control records (2017, 2018) showed that the laboratory did not include two levels of control each 8 hours of operation in the shift #3 on May 13, 2017 and on January 27, 2018. b. The testing personnel (Medical Technologist #3) confirmed on April 10, 2018 at 3:00 PM, that the testing personnel of the shift #3 did not include two levels of control in the 8 hours of operation on May 13, 2017 and on January 27, 2018. c. The laboratory processed and reported the following PT patient's specimens in the shift #3: #569814 on May 13,

	2017 at 2:00 am, patient specimen # 647840 on 11:42 pm on January 27, 2018, patient specimen # 647857 at 12:50 am and patient specimen #647870 at 2:24 am on January 28, 2018. d. The coagulation procedures manual did not establish a specific schedule of time to ensure that the laboratory run the two levels of coagulation control each 8 hours of operation and each time a reagent is changed. e. It was observed, on April 10, 2018 at 3:00 PM, that the laboratory posted in the wall (near the CA1500 system), the schedule of time when the laboratory should run the PT control materials: Shift # 1 - 6: 00 am to 7:00 am Shift # 2 - 2:00 pm to 3:00 pm Shift # 3- 10:00 pm to 11:00 pm f. The laboratory director confirmed on April 10, 2018 at 3:10 PM, that the coagulation procedures manual did not establish a specific schedule of time to ensure that the laboratory runs the two levels of coagulation control each 8 hours of operation and each time a reagent is changed. (2) Based on coagulation procedures manual, Prothrombin Time (PT) quality control records (years 2017 to 2018), International Normalized Ration (INR) values results records review and laboratory director interview on April 10, 2018 at 3:20 PM, it was determined that the laboratory failed to have a written procedures to determine and calculate the INR results of 3,112 out of 3,112 patients specimens from May 1, 2017 to April 10, 2018. The findings include: a. The laboratory reported the INR value results by the CA 1500 system. b. The PT quality control records showed that the laboratory determined the geometric mean of the PT population for the new lot of Innovin Dade (Lot 53938) in May 2017. c. The coagulation procedures manual showed no written procedures to determine and calculate the INR value result. Also, the laboratory did not have a protocol to periodically verify for each thromboplastin lot number in use, the correct normal patient PT mean is being used for calculating the INR value. d. The laboratory director confirmed on April 10, 2018 at 3:20 PM, that the coagulation procedures manual did not have a written procedure to determine and calculate the INR value result or a protocol to periodically verify the correct normal patient PT mean used for calculating the INR value. e. The laboratory reported 3,112 out of 3,112 INR patient's results from May 1, 2017 to April 10, 2018.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on histopathology procedures manual, quality control records review from January 11, 2016 to April 10, 2018 and laboratory personnel interview, it was determined that the histopathology laboratory did not take nor document any correction action when the room temperature and relative humidity was out of range. The findings include: 1. The laboratory procedures manual establishes that the laboratory must monitor and document the room temperature (18 C - 35 C) and relativity humidity (60%) each day of surgery. 2. Review of histopathology quality control records from January 11, 2016 to December 19, 2016, showed that 13 out of

	15 room temperatures were below of range (18 C), 12 out of 21 room temperatures from January 23, 2017 to December 29, 2017 were below of range (18 C) and 4 of 4 room temperatures from January 22, 2018 to April 10, 2018 were below of range (18 C). 3. Review of histopathology quality control records from January 11, 2016 to December 19, 2016, showed that the 4 out of 15 relativity humidity were over of range (60%), 11 out of 21 relativity humidity from January 23, 2017 to December 29, 2017 were over of range and 4 of 4 room temperatures from January 22, 2018 to April 10, 2018 were over of range. 4. The laboratory personnel confirmed on April 10, 2018, that the room temperature was below of range and relativity humidity was over of range and did not perform nor document remedial actions those days.
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: 1. Based on direct observation, Puerto Rico Proficiency Testing Program results, R & B body fluid hematology control systems manufacturer's instructions, Hematology procedures manual, body fluid testing and quality control records, R & B body fluid hematology control Kit insert records, hematology quality control records, platelets quality control graphs records, coagulation procedures manual, Prothrombin Time (PT) quality control records (2017, 2018), International Normalized Ration (INR) values results records review, HIV tests, general chemistry tests, laboratory director and testing personnel (Medical Technologist #3)interview on April 10, 2018 at 3:20 PM, it was determined that the laboratory director failed to fulfill his responsibilities and duties to ensure compliance with the laboratory analytical system and quality assessment requirements. The findings include: a. The laboratory director did not comply with the requirements of the Puerto Rico Proficiency Testing Program results. Refer to D 6092. b. The laboratory director did not comply with the analytical systems requirements. Refer to D 6093. c. The laboratory director did not assure that the verifications were performed by the testing personnel and did not evaluated the data obtained by the manufacturer's specialist. Refer to D6086 d. The laboratory director did not assure the testing personnel performed the test methods as required. Refer to D6087
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method. This STANDARD is not met as evidenced by: Based on review of Alere Determine HIV 1/2 Ag/Ab Combo verification of performance specification review and interview with the testing personnel MT' 7 and 8, it was determined that the laboratory director did not assure that the verifications were performed by the testing personnel and did not evaluate the data obtained by the manufacturer's specialist. Refer to D 5421.

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 review of HIV test, routine chemistry tests and interview with the laboratory director and the testing personnel on April 10, 2018, it was found that the laboratory director did not assure the testing personnel performed the test methods as required. Refer to D 5401- The testing personnel did not check the room temperature before perform HIV tests. D 5429- The testing personnel did not perform the Vitros 560 preventive maintenance D-5439- The testing personnel did not perform calibration verification procedures for dTIBC D-5449- The testing personnel did not include quality control material when HIV were processed.
D6092	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iv) The laboratory director must ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on Puerto Rico Proficiency Testing (PT) Program (2016,2017) records review and laboratory director interview on April 10, 2018 at 4:00 PM, it was determined that the laboratory failed to take and document remedial action when it obtained unacceptable analyte score of routine chemistry and toxicology proficiency testing results in the first PT event (February 2017). The findings include: 1. The laboratory did not take nor document remedial action when it obtained unacceptable analyte score of proficiency testing results for total bilirubin (80 %) and for lactate dehydrogenase (80 %) proficiency testing results in the first PT event (February 2017). Refer to D 2094. 2. The laboratory did not take nor document remedial action when it obtained unacceptable analyte score of proficiency testing results for valproic acid (80 %) proficiency testing results in the first PT event (February 2017). Refer to D D 2116.
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: 1. Based on direct observation, R & B body fluid hematology control systems manufacturer's instructions, Hematology procedures manual, body fluid testing and quality control records, R & B body fluid hematology control Kit insert records, hematology quality control records, platelets quality control graphs records, coagulation procedures manual, Prothrombin Time (PT) quality control records (2017, 2018), International Normalized Ration (INR) values results records review,

	laboratory director and testing personnel (Medical Technologist #3)interview on April 10, 2018 at 3:20 PM, it was found that the laboratory director failed to ensure compliance with the analytic system requirements for the Hematology specialty. The finding includes: a. The laboratory director failed to ensure compliance with the analytic system requirements of Hematology specialty. Refer to D 5024. 2. Based on review of the Alere Determine HIV 1/2 Ag/AB Combo test quality control records and interview with the laboratory director and the testing personnel on April 10, 2018, at 2:00PM, it was determined that the laboratory did not assure, that the quality control procedure for the HIV performed by the Alere Determine reagent, complied with the existing regulations. Refer to D 5449- The laboratory director stated that a IQCP was established for the HIV tests, however no IQCP was evaluated nor prepared. The laboratory director established a control frequency less than the existing CLIA regulation.
D6141	GENERAL SUPERVISOR CFR(s): 493.1459 The laboratory must have one or more general supervisors who are qualified under 493.1461 of this subpart to provide general supervision in accordance with 493.1463 of this subpart. This CONDITION is not met as evidenced by: Based on review of the Form CMS-209 and interview with the laboratory director, it was found that the general supervisor position was not filled. The findings include: a. The Form CMS-209 filled during the survey on April 10, 2018 did not include any personnel assigned to the general supervisor position. b. The laboratory director stated that beside her position as a director, she was the technical supervisor also. Included in the CMS -209 .
D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: 1. Based on direct observation, R & B body fluid hematology control systems manufacturer's instructions, Hematology procedures manual, body fluid testing and quality control records, R & B body fluid hematology control Kit insert records, hematology quality control records, platelets quality control graphs records, coagulation procedures manual, Prothrombin Time (PT) quality control records (2017, 2018), International Normalized Ration (INR) values results records review, laboratory director and testing personnel (Medical Technologist #3) interview on April 10, 2018 at 3:20 PM, it was determined that testing personnel failed to fulfill her responsibilities and duties to ensure compliance with the laboratory analytical system requirements for the Hematology specialty. Refer to D 6177. 2. Based on HIV and routine chemistry test records review and interview with the laboratory director and the testing personnel on April 10, 2018, it was determined that testing personnel failed

	to fulfill her responsibilities and duties to ensure compliance with the laboratory analytical system requirements for general Immunology tests (HIV) and routine chemistry tests. Refer to D6177
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 direct observation, R & B body fluid hematology control systems manufacturer's instructions, Hematology procedures manual, body fluid testing and quality control records, R & B body fluid hematology control Kit insert records, hematology quality control records, platelets quality control graphs records, coagulation procedures manual, Prothrombin Time (PT) quality control records (2017, 2018), International Normalized Ration (INR) values results records review, laboratory director and testing personnel (Medical Technologist #3)interview on April 10, 2018 at 3:20 PM, it was determined that testing personnel failed to follow quality control procedures for the Hematology specialty. The finding includes: 1. The laboratory did not meet the analytic system requirements of Hematology specialty. Refer to D 5024 2. Based on review of HIV test, routine chemistry tests and interview with the laboratory director and the testing personnel on April 10, 2018, it was found that the testing personnel did not follow quality control requirements. Refer to D 5401- The testing personnel did not check the room temperature before perform HIV tests. D 5429- The testing personnel did not perform the Vitros 560 preventive maintenance D-5439- The testing personnel did not perform calibration verification procedures for dTIBC D 5449- The testing personnel did not include control material when HIV were performed.