Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0875318	01/10/2019
Name of Provider or Supplier	**Street Address, City, State**	
Hospital Menonita Humacao	Font Martelo 300, 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
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on manufacturer's instructions of Influenza A & B test (OSOM Ultra FLU A&B Test), virology quality control records review and laboratory general supervisor and testing personnel interview on January 10, 2019 at 10:22 AM, it was determined that the laboratory failed to follow the manufacturer's instruction for evaluate and document the internal quality control (internal positive procedural control) when performed Influenza A & B test by OSOM Ultra FLU A&B Test method. The findings include: 1. The laboratory performed Influenza A & B test by OSOM Ultra FLU A&B Test method. 2. The manufacturer's establishes that the laboratory must include a positive and a negative control material, evaluate the internal quality control (internal positive procedural control) for valid the Influenza A&B tests. 3. The Influenza A&B tests quality control records showed that the laboratory did not evaluate and document the internal quality control (internal positive procedural control) from January 1, 2018 to January 10, 2019. 4. The laboratory performed and reported 1,651 Influenza A& B patient's samples tests during those months. 5. The general supervisor confirmed on January 10, 2019, that the laboratory did not evaluate and document the internal quality control from January 1, 2018 to January 10, 2019.
D3001	FACILITIES CFR(s): 493.1101(a)(1) The laboratory must be constructed, arranged, and maintained to ensure the space, ventilation, and utilities necessary for conducting all phases of the testing process.

	This STANDARD is not met as evidenced by: Based on observation of the laboratory working areas and general supervisor interview on January 10, 2019 at 8:30 AM, it was determined that the laboratory failed to ensure that an adequate space were available for handling and testing of patient samples in the routine chemistry, endocrinology and toxicology areas. The findings include: 1. On January 10, 2019 at 8:30 AM, its observed that the laboratory have two working areas for handling and testing of routine chemistry, endocrinology and toxicology patient samples. 2. The size of one out of two working areas is approximately 11 ' (length) and 7' (width). In this area, the laboratory located the system Cobas e- 411 in the front of the Integra 800 system. The testing personnel have a working space of approximately 7 ' (length) and 2' (width) to process the patients specimens by the two systems. The area did not have a counter top for the patients specimens handling. The testing personnel used the top of the Integra 800 system to placed the rack with the patients serum specimens. Also, the printer of this area was located in the floor. 3. The size of the second area is approximately 6 ' (length) and 3' (width). This areas includes the Cobas c501 system, two waters tanks, one refrigerator and one chair, 6 boxes with Cobas c501 system reagents and devices (5 boxes located at the top of the refrigerator and one large box located in the floor). The area did not have a counter top for the patients specimens handling. 4. The general supervisor confirmed on January 10, 2019 at 8:30 AM, that the those testing areas were very crowded and letting few space to process the routine chemistry, endocrinology and toxicology patient specimens. 5. The laboratory processed and reported 2530 patient specimens by the Cobas e-411 system from August 1, 2018 to November 30, 2018; 171,565 patient specimens by the Integra 800 system from January 1, 2018 to January 10, 2019 and 26, 034 patient specimens by the Cobas c501 system from October 1, 2018 to December 31, 2018.
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 review of personnel file and hospital staff interview on January 10, 2019 at 12:00 PM, it was determined that the laboratory failed to follow written policies to assess the blood gases superviosr competency since January 31, 2015. The findings include : 1. On January 10, 2019 at 12:00 PM, the personnel file showed that the annual competency of the blood gases supervisor was not performed since January 31, 2015. 2. The hospital staff confirmed on January 10, 2019 at 12:00 PM, that the competency of the blood gases supervisor was not performed since January 31, 2015.
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 and interview with the blood gases supervisor on January 10, 2019 at 12:00 PM, it was determined that laboratory failed to follow the established Quality Assessment Program to monitor and evaluate the requirements for general laboratory systems (testing personnel annual competence). Refer to D 5209 (The laboratory failed to follow written policies to assess the blood gases superviosr competency since January 31, 2015).
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 Quality Assessment (QA) records (years 2017 to 2018) review and interview with the blood gases tests supervisor on January 10, 2019 at 12:00 PM, it was determined that the laboratory failed to follow the established Quality Assessment Program to monitor and evaluate the requirement for pre- analytic systems (tests request). The findings include: 1.On January 10, 2019 at 12:00 PM, the quality assessment program showed that evaluations to patient test request must be evaluated every month. 2. Review of the quality assessment records showed that the laboratory did not perform the patient test evaluation since October 2018. 3. The blood gases tests supervisor confirmed on January 10, 2019 at 12:00 PM, that the laboratory did not perform the patient test request evaluations since October 2018.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by:

	Based on calibration verification records (years 2017 and 2018) review, interview with the general supervisor of routine chemistry tests on January 10, 2019 at 8:50 AM and interview with the supervisor of the blood gases tests on January 10, 2019 at 12: 00 PM, it was determined that the laboratory failed to evaluate statistically the calibration verification procedures for the routine chemistry tests performed on 11/13 /2018 by the Cobas e-411 system and the calibration verification procedures for the blood gases tests performed on December 10, 2018 by the Cobas b 221. The findings include: 1. The calibration verification records showed that the laboratory failed to evaluated statistically the calibration verification procedures for the routine chemistry tests performed on 11/13/2018 by the Cobas e-411 and the calibration verification procedures for the blood gases tests performed on December 10, 2018 by the Cobas b 221. 2. The general supervisor of routine chemistry tests confirmed on January 10, 2019 at 8:50 AM, that the laboratory did not evaluate statistically the calibration verification procedures for the routine chemistry tests performed on 11/13/2018 by the Cobas e-411. 3. The supervisor of the blood gases tests confirmed on January 10, 2019 at 12:00 PM, that the laboratory did not evaluate statistically the calibration verification procedures for the blood gases tests performed on December 10, 2018 by the Cobas b 221. 4. The laboratory processed 526 patients specimens by the Cobas e-411 system during November 2018 and 3343 patients specimens by the Cobas b 221 during the year 2018.
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 Cobas b 221 manufacturer's instructions, lack of ambient air pressure verification records and interview with the blood gases superviosr on January 10, 2019 at 12:00 PM, it was determined that the laboratory failed to ensure that the manufacturer operation condition of ambient air pressure were maintained when 3,343 patients blood gases specimens were processed by the Cobas b 221 system from January 1, 2018 to December 31, 2018. The findings include: 1. On January 10, 2019 at 2019, the Cobas b 221 manufacturer instructed the laboratory as operation condition an ambient air pressure from 526 to 797 mmHg. 2. The laboratory did not verify the ambient air pressure from January 1, 2018 to December 31, 2018. 3. The blood gases superviosr confirmed that the laboratory did not verify the ambient air pressure from January 1, 2018 to December 31, 2018. 4. The laboratory processed and reported 3,343 patients blood gases specimens by the Cobas b 221 system from January 1, 2018 to December 31, 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 laboratory procedures manual, hematology and immunohematology quality control records review from January 1, 2018 to January 10, 2019 and laboratory general supervisor and testing personnel interview on January 10, 2019 at 10:53 AM, it was determined that the laboratory failed to monitor and document the laboratory's voltages, refrigerator and freezer temperatures. The findings include: 1. The laboratory procedures manual establishes that the laboratory monitor and document daily the voltage, refrigerator and freezer temperatures. 2. From December 27, 2018 to December 31, 2018, the laboratory did not monitor and document the daily the voltage, refrigerator and freezer temperatures. 3. The laboratory general supervisor and testing personnel confirmed on January 10, 2019, that the laboratory did not monitor and document the voltage, refrigerator and freezer temperatures those days.
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 validation records (year 2018) review of the Cobas e-411 and Cobas c 501 systems for the routine chemistry, endocrinology and toxicology tests and general superviosr interview on January 10, 2019 at 9:40 AM, it was determined that the laboratory failed to verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population before reporting 2,004 patient specimens by the Cobas e-411 system for routine chemistry, special chemistry and endocrinology tests results from August 2018 to October 2018 and before reporting 26,034 patient specimens by the Cobas c 501 system for routine chemistry and toxicology tests results October 1, 2018 to January 10, 2019. The findings include: 1. On January 10, 2019 at 9:40 AM, the Cobas e-411 system validation records showed that the laboratory laboratory performed the validation procedures on April 30, 2018 and it did not verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. The laboratory processed patients specimens for routine chemistry, special chemistry and endocrinology tests since July 1, 2018. 2. On January 10, 2019 at 9:40 AM, the Cobas c 501 system validation records showed that the laboratory laboratory performed the validation procedures on June 30, 2018 and it did not verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. The laboratory processed patients specimens for routine chemistry and toxicology tests since September 1, 2018. 3. The general supervisor laboratory director confirmed on January 10, 2019 at 9:40 AM, that the laboratory did not verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population before reporting patient specimens by the Cobas e-411

	and the Cobas c 501 systems. 4. The laboratory processed and reported 2,004 patient specimens by the Cobas e-411 system from August 1, 2018 to November 30, 2018 and 26, 034 patient specimens by the Cobas c501 system from October 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 written procedures, preventive maintenance records (years 2018) review and interview with the general superviosr on January 10, 2019 at 9:40 AM, it was determined that the laboratory failed to follow written instructions for the preventive maintenance when the following patients specimens were processed and reported: 2,004 patients specimens by the Cobas e-411 system from August 1, 2018 to November 30, 2018; 171,565 patients specimens by the Integra 800 system from January 1, 2018 to January 10, 2019 and 26, 034 patients specimens by the Cobas c501 system from October 1, 2018 to January 10, 2019. The findings include: 1. On January 10, 2019 at 9:40 AM, the preventive maintenance records showed that the laboratory did not follow written instruction for preventive maintenance of the following systems: a. Cobas e-411 system, the laboratory did not perform the monthly preventive maintenance in August 2018, September 2018 and October 2018. b. Integra 800 system, the laboratory did not perform the following preventive maintenance from January 1, 2018 to January 10, 2019: quarterly, every 6 months and every 8 months. c. Cobas c 501 system, the lab did not perform the daily photometer checks reading from October 1, 2018 to January 10, 2019; did not perform 3 out of 4 weekly preventive maintenance during October 2018; did not perform 2 out of 2 weekly preventive maintenance during November 2018; not performed the every 2 months preventive maintenance in schedule during the November 2018 and did not performed the quarterly preventive maintenance in schedule during December 2018. 2. The general superviosr confirmed on January 10, 2019 at 9:40 AM, that the preventive maintenance records did not include the required documentation. she stated that the preventive maintenance was performed but not documented. 3. The laboratory processed and reported 2,004 patient specimens by the Cobas e-411 system from August 1, 2018 to November 30, 2018; 171,565 patient specimens by the Integra 800 system from January 1, 2018 to January 10, 2019 and 26, 034 patient specimens by the Cobas c501 system from October 1, 2018 to December 31, 2018. 11586 Based on laboratory procedures manual, hematology and immunohematology quality control records review from January 1, 2018 to January 10, 2019 and laboratory general supervisor and testing personnel interview on January 10, 2019 at 10:53 AM, it was determined that the laboratory failed to perform and document daily the preventive maintenance of the microscope, refrigerator and eye wash station. The findings include: 1. The laboratory procedures manual establishes that the laboratory perform and document daily the preventive maintenance of the microscope, refrigerator and eye wash station. 2. From December 27, 2018 to December 31, 2018, the laboratory did not perform and document the daily the preventive maintenance of the microscope, refrigerator and eye wash station. 3. The laboratory general supervisor

	and testing personnel confirmed on January 10, 2019, that the laboratory did not perform and document the preventive maintenance of microscope, refrigerator and eye wash station those days.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(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 postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on Quality Assessment (QA) records (years 2017 to 2018) review and interview with the blood gases tests supervisor on January 10, 2019 at 12:00 PM, it was determined that the laboratory failed to follow the established Quality Assessment Program to monitor and evaluate the requirement for post- analytic systems (Turn around time and the interface results verification). The findings include: 1.On January 10, 2019 at 12:00 PM, the quality assessment program showed that evaluations for the turn around time (TAT) and the interface results verification must be evaluated every month. 2. Review of the quality assessment records showed that the laboratory did not perform the TAT nor the interface results verification since October 2018. 3. The blood gases tests supervisor confirmed on January 10, 2018 at 12:00 PM, that the laboratory did not perform the TAT nor the interface results verification since October 2018.
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 observations, manufacturer's instructions, quality control records, quality assessment review and laboratory general supervisor and testing personnel interview on January 10, 2019 at 12:30 PM, it was determined that the laboratory director failed to fulfill his responsibilities and duties to ensure compliance with the laboratory facilities, analytical system and quality assessment system. The findings include: 1. The laboratory director failed to fulfill his responsibilities and duties to ensure compliance with the laboratory facilities (physical plant) requirements. Refer to D6083. 2. The laboratory director did not comply with the requirement for analytical systems and quality assessment requirements. Refer to D6093 and D6094.
D6083	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(2) The laboratory director must ensure that the physical plant and environmental conditions of the laboratory are appropriate for the testing performed. This STANDARD is not met as evidenced by:

	Based on observation of the laboratory working areas and general supervisor interview on January 10, 2019 at 8:30 AM, it was determined that the laboratory director failed to ensure that an adequate space were available for handling and testing of patient samples in the routine chemistry, endocrinology and toxicology areas. Refer to D 3001.
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 calibration verification records (years 2017 and 2018), Cobas b 221 manufacturer's instructions, lack of ambient air pressure verification records, validation records (year 2018) review of the Cobas e-411 and Cobas c 501 systems for the routine chemistry, endocrinology and toxicology tests, written procedures, preventive maintenance records (years 2018 and 2019) review and interview with the supervisor of the blood gases tests and with the the general supervisor of routine chemistry tests on January 10, 2019 at 12:00 PM, it was determined that the laboratory director failed to ensure compliance with the requirements for routine chemistry, endocrinology, toxicology and blood gases analytic systems. Refer to D 5403 (The laboratory failed to evaluate statistically the calibration verification procedures for the routine chemistry tests performed on 11/13/2018 by the Cobas e-411 system and the calibration verification procedures for the blood gases tests performed on December 10, 2018 by the Cobas b 221). Refer to D 5405 (The laboratory failed to ensure that the manufacturer operation condition of ambient air pressure were maintained when 3,343 patients blood gases specimens were processed by the Cobas b 221 system from January 1, 2018 to December 31, 2018). Refer to D5413 (The laboratory failed to monitor and document the laboratory's voltages, refrigerator and freezer temperatures from December 27 , 2018 to December 31, 2018). Refer to D 5421 (The laboratory failed to verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population before reporting 2,004 patient specimens by the Cobas e-411 system for routine chemistry, special chemistry and endocrinology tests results from August 2018 to October 2018 and before reporting 26,034 patient specimens by the Cobas c 501 system for routine chemistry and toxicology tests results October 1, 2018 to January 10, 2019). Refer to D 5429 (The laboratory failed to follow written instructions for the preventive maintenance when the following patients specimens were processed and reported: 2,004 patients specimens by the Cobas e-411 system from August 1, 2018 to November 30, 2018; 171,565 patients specimens by the Integra 800 system from January 1, 2018 to January 10, 2019 and 26, 034 patients specimens by the Cobas c501 system from October 1, 2018 to January 10, 2019). Refer to D5429 (The laboratory failed to perform and document the preventive maintenance of the microscope, refrigerator and eye wash station from December 27, 2018 to December 31, 2018).
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 (years 2017 to 2018) review and interview with the blood gases tests supervisor on January 10, 2019 at 12:00 PM, it was determined that the laboratory director failed to ensure that the laboratory follow the established Quality Assessment Program to monitor and evaluate the requirement for general laboratory system, pre- analytic systems and post-analytic system. Refer to D 5291, D 5391 and D 5891.
D6117	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(4) The technical supervisor is responsible for establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results. This STANDARD is not met as evidenced by: Based on calibration verification records (years 2017 and 2018), Cobas b 221 manufacturer's instructions, lack of ambient air pressure verification records, validation records (year 2018) review of the Cobas e-411 and Cobas c 501 systems for the routine chemistry, endocrinology and toxicology tests, written procedures, preventive maintenance records (years 2018 and 2019) review and interview with the supervisor of the blood gases tests and with the the general supervisor of routine chemistry tests on January 10, 2019 at 12:00 PM, it was determined that technical superviosr failed to ensure compliance with the requirements for routine chemistry, endocrinology, toxicology and blood gases analytic systems. Refer to D 5403, D 5405, D 5421 and D 5429.
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 calibration verification records (years 2017 and 2018), Cobas b 221 manufacturer's instructions, lack of ambient air pressure verification records, validation records (year 2018) review of the Cobas e-411 and Cobas c 501 systems for the routine chemistry, endocrinology and toxicology tests, written procedures, preventive maintenance records (years 2018 and 2019) review and interview with the supervisor of the blood gases tests and with the the general supervisor of routine chemistry tests on January 10, 2019 at 12:00 PM, it was determined that the general superviosr failed to ensure compliance with the requirements for routine chemistry, endocrinology, toxicology and blood gases analytic systems. Refer to D 5403, D 5405, D 5421 and D 5429.

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 calibration verification records (years 2017 and 2018), Cobas b 221 manufacturer's instructions, lack of ambient air pressure verification records, validation records (year 2018) review of the Cobas e-411 and Cobas c 501 systems for the routine chemistry, endocrinology and toxicology tests, written procedures, preventive maintenance records (years 2018 and 2019) review and interview with the supervisor of the blood gases tests and with the the general supervisor of routine chemistry tests on January 10, 2019 at 12:00 PM, it was determined that the testing personnel failed to follow quality control procedures for routine chemistry, endocrinology, toxicology and blood gases analytic systems. Refer to D 5403, D 5405, D 5421 and D 5429. Based on hematology and immunohematology quality control records review from January 1, 2018 to January 10, 2019 and laboratory general supervisor and testing personnel interview on January 10, 2019 at 11:58 AM, it was determined that testing personnel failed to follow quality control procedures for hematology and immunohematology analytic system. Refer to D5413 and D5429.