Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0945805	03/13/2019
Name of Provider or Supplier	**Street Address, City, State**	
Centro De Servicios De Salud Ryder	Calle Munoz Rivera Final, San Lorenzo, 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
D2128	HEMATOLOGY CFR(s): 493.851(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 (P.R. PTP) records(years 2017 and 2018) review and testing personnel interview on March 13, 2019 at 12:20 PM, it was determined that the laboratory failed to take and document corrective actions when it obtained unsatisfactory results in hematology specialties. The findings include: 1. On March 13, 2019 at 12:20 PM, the P.R. PTP showed that the laboratory obtained unsatisfactory results of 60 percent for white blood cell count in the second event (July 2018). No remedial actions were taken. 2. The testing personnel confirmed on on March 13, 2019 at 12:20 PM, that the laboratory failed to take remedial actions when it obtained this unsatisfactory results for white blood cell count in July 2018.
D3037	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years. This STANDARD is not met as evidenced by: Based on Puerto Rico Proficiency Testing Program (P.R. PTP) records(years 2017

	and 2018) review and testing personnel interview on March 13, 2019 at 12:30 PM, it was determined that the laboratory failed to retain all proficiency testing records for at least 2 years. The findings include: 1. The P.R. PTP records were reviewed from February 2017 to December 2018. 2. On March 13, 2019 at 12:30, the laboratory did not have available the P.R. PTP results for the proficiency testing first event of routine chemistry tests (February 2018). 3. The testing personnel confirmed on March 13, 2019 at 12:30 PM, that the laboratory did not have available this records.
D5016	ROUTINE CHEMISTRY CFR(s): 493.1210 If the laboratory provides services in the subspecialty of Routine Chemistry, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493. 1267, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on Bio-Rad controls materials package insert, laboratory freezer temperature chart records (years 2018 and 2019), routine chemistry quality control records (years 2016, 2017 and 2018) review and testing personnel interview on March 13, 2019 at 10: 50 AM, it was determined that the laboratory failed to ensure compliance with the analytic system requirements for routine chemistry from January 2017 to March 2019. Refer to D 5413 (The laboratory failed to follow manufacturer's instructions for the proper temperature storage of the Bio-Rad controls material in 437 out of 437 days from January 2018 to March 13, 2019). Refer to D 5439 (The laboratory failed to perform at least every 6 months the calibration verification procedures for the sodium (Na), potassium (K) and chloride (Cl) tests when it processed and reported 10,864 out of 10,864 patients specimens for comprehensive metabolic panel (CMP) tests by the Dimension X pand system during the year 2017). Refer to D 5481 (The laboratory failed to take and document corrective actions when the Levey Jennings charts of the HDL-cholestrol and total bilirubin showed controls values not meet the laboratory's criteria for acceptability before it reporting 171 out of 171 patients specimens for HDL-cholesterol and Total bilirubin results from August 31, 2018 to January 31, 2019).
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 Coulter LH 500 system manufacturer' instructions, Scal calibrator material package insert, calibration records (years 2017 and 2018) review for the Coulter LH 500 system and interview with the testing personnel on March 13, 2019 at 11:20 AM, it was determined that the laboratory failed to ensure compliance with the analytic system requirements for CBC tests. Refer to D 5417 (The laboratory used the Scal calibrator material that have exceeded the expiration date in one out of two calibration procedures performed for the Coulter LH 500 system during the year 2018). Refer to

	D 5437 (The the laboratory used calibration material not appropriate when it performed one out of two calibration procedures of the Coulter LH 500 during 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 Bio-Rad controls materials package insert, laboratory freezer temperature chart records (years 2018 and 2019) review and testing personnel interview on March 13, 2019 at 10:50 AM, it was determined that the laboratory failed to follow manufacturer's instructions for the proper temperature storage of the Bio-Rad controls material in 437 out of 437 days from January 2018 to March 13, 2019. The findings include: 1. The laboratory used the Bio-Rad controls materials to monitoring the quality control of the routine chemistry tests processed and reported by the Dimension Xpand system from January 2018 to March 13, 2019. 2. The Bio-Rad controls materials manufacturer package insert instructed the laboratory to storage the Bio-Rad controls materials at temperature range from -20 C to -70 C. 3. On March 13, 2019 at 10:50 AM, review the laboratory freezer temperature chart records (years 2018 and 2019) showed that the temperature of the freezer was out of the require range for the Bio-Rad controls materials storage in 437 out of 437 days from January 2018 to March 13, 2019. The laboratory freezer temperature chart records showed a temperature range documented form 15 C to 16 C. 4. The testing personnel confirmed on March 13, 2019 at 10:50 AM, that the laboratory did not follow the manufacture instruction for the proper storage of the Bio-Rad controls materials from January 2018 to March 13, 2019. 5. The laboratory processed and reported 22,749 out of 22,749 routine chemistry tests by the Dimension Xpand system during the yar 2018.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on Coulter LH 500 system manufacturer' instructions, Scal calibrator material package insert, calibration records (years 2017 and 2018) review for the Coulter LH 500 system and interview with the testing personnel on March 13, 2019 at 11:20 AM, it was determined that the laboratory used the Scal calibrator material that have exceeded the expiration date in one out of two calibration procedures performed for the Coulter LH 500 system during the year 2018. The findings include: 1. The laboratory analyzed and reported complete blood count (CBC) patient's specimens by

	the Coulter LH 500 system. 2. The Coulter LH 500 system manufacturer's instructed the laboratory to use the Scal calibrator material for the calibration procedures. 3. On March 13, 2019 at 11:20 AM, the calibration records of the Coulter LH 500 system showed that the laboratory calibrated this system on July 20, 2018 and on October 19, 2018. 3. The Scal calibrator package insert showed that the laboratory used the Scal calibrator material (lot 4745) with exceeded the expiration date (July 14, 2018) for the calibration of the Coulter LH 500 system performed on July 20, 2018. 4. The testing personnel confirmed on March 13, 2019 at 11:20 AM, that the laboratory used the Scal calibrator material (lot 4745, exp. July 14, 2018)) that have exceeded the expiration date when it performed the calibration procedures of the Coulter LH 500 system on July 20, 2018. 5. The laboratory processed and reported 485 out of 485 patients specimens for CBC from July 20, 2018 to October 18, 2018.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on Coulter LH 500 system manufacturer' instructions, Scal calibrator material package insert, calibration records (2017, 2018) review for the Coulter LH 500 system and interview with the testing personnel on March 13, 2019 at 11:20 AM, it was determined that the laboratory used calibration material not appropriate when it performed one out of two calibration procedures of the Coulter LH 500 during year 2018. The finding includes: 1. The laboratory used calibrator material with exceeded the expiration date when it performed one of two calibration procedures for the Coulter LH 500 system during the year 2018. Refer to D 5417.
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 routine chemistry quality control records (years 2016, 2017 and 2018) review and testing personnel interview on March 13, 2019 at 10:10 AM, it was determined that the laboratory failed to perform at least every 6 months the calibration verification procedures for the sodium (Na), potassium (K) and chloride (Cl) tests when it processed and reported 10,864 out of 10,864 patients specimens for comprehensive metabolic panel (CMP) tests by the Dimension X pand system during the year 2017. The findings include: 1. on March 13, 2019 at 10:10 AM the routine chemistry quality control records showed that the laboratory did not perform at least every 6 months the calibration verification procedures for the Na, K and Cl tests by the Dimension X pand system during the year 2017. 2. The testing personnel confirmed on March 13, 2019 at 10:10 AM, that the laboratory did not have records available for the calibration verification procedures of the Na, K and Cl tests by the Dimension X pand system during the year 2017. 3. The laboratory processed and reported 10,864 out of 10,864 CMP patients specimens tests by the Dimension X pand system during the year 2017.
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 pregnancy tests testing records (years 2017, 2018 and 2019) review and interview with the testing personnel on March 13, 2019 at 11:40 AM, it was found that the laboratory failed to include at least once a day a negative and a positive control materials when two out of two patients specimens were tested and reported from July 28, 2017 to December 27, 2018. The findings include: 1. On March 13, 2019 at 11:40 AM, the pregnancy tests testing records showed that the the laboratory did not include at least once a day the negative nor the positive control material when two out of two patients specimens were tested and reported from July 28, 2017 to December 27, 2018: patient specimen #18-5741 on December 27, 2018 and patient specimen # 17- 2235 on July 28, 2017. 2. The testing personnel confirmed on March 13, 2019 at 11:40 AM, that the records showed no controls results results, but she stated that the control materials were run but not documented.
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 routine chemistry quality control records review and testing personnel interview on March 13, 2019 at 10:10 AM, it was determined that the laboratory failed to take and document corrective actions when the Levey Jennings charts of the HDL-cholestrol and total bilirubin showed controls values not meet the laboratory's criteria for acceptability before it reporting 171 out of 171 patients specimens for HDL-cholesterol and Total bilirubin results from August 31, 2018 to January 31, 2019. The findings include: 1. The laboratory processed the HDL-cholestrol and total bilirubin tests by the Dimension Xpand system. 2. On March 13, 2019 at 10:10 AM, the Levey Jennings of the HDL-cholestrol and total bilirubin showed that the following days the controls values did not meet the laboratory's criteria for acceptability. However, the laboratory reported patients test results and corrective actions were not taken: a. From August 31, 2018 to September 30, 2018; the Levey Jennings chart of the level I of total bilirubin control material showed 13 out of 22 days when the control values exceeded the two standard deviation (2 SD); the laboratory reported 61 patients specimens for total bilirubin test. b. During December 2018; the Levey Jennings chart of the level I of HDL-cholesterol control material showed 5 out of 22 days when the control values exceeded 2 SD, the Levey Jennings chart of the level II of HDL-cholesterol control material showed 16 out of 22 days when the control values exceeded the 2 SD; the laboratory reported 37 patients specimens for HDL-cholesterol. c. From December 31, 2018 to January 31, 2019, the Levey Jennings chart level I of total bilirubin control material showed 17 out of 24 days when the control values exceeded the 2SD; the laboratory reported 73 patients specimens for total bilirubin test. 3. The testing personnel confirmed on March 13, 2019 at 10:10 AM, that those Levey Jennings showed trends.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on quality assessment (QA) program, QA assessment records review (years 2017, 2018 and 2019) and interview with the laboratory director on March 13, 2019 at 12:38 PM, it was determined that the laboratory failed to have a written procedures to monitor and evaluate the patient tests results for inconsistencies with the patient information since January 2017. The findings include: 1. On March 13, 2019 at 12:38 PM, the laboratory did not have a written procedures to monitor evaluate the patient tests results which showed any inconsistency related to patient age, sex, diagnosis or pertinent clinical data, distribution of patient test results and relationship with other test parameters since January 2017. 2. The laboratory director confirmed on March 13, 2019 at 12:38 PM, that the laboratory did not have the required protocol.
D5805	TEST REPORT

	CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on laboratory test reports records (years 2018 to 2018) review and laboratory director interview on March 13, at 12:38 PM, it was determined that the laboratory failed to indicate the address of the laboratory location in 22,749 reports for routine chemistry tests and 2,946 reports for urinalysis tests results that were reported by the laboratory from January 1, 2018 to December 31, 2018. The findings include: 1. On March 13, at 12:38 PM, the test report records showed that the laboratory did not indicate the address of the laboratory location in the 100 per cent of the routine chemistry and urinalysis tests results reported by the laboratory from January 2018 to March 12, 2019. 2. The laboratory director stated on March 13, at 12:38 PM, that she did not realize that those results did not include the laboratory address. 3. The laboratory reported 22,749 routine chemistry results and 2,946 urinalysis results from January 1, 2018 to December 31, 2018.
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) program, QA assessment records review (years 2017, 2018 and 2019) and interview with the testing personnel on March 13, 2019 at 12:38 PM, it was determined that the laboratory did not have written protocol to assess the test reports information since January 2017. The findings include: 1. The laboratory did not have a written procedures to monitor the test reports information since January 2017. 2. The laboratory failed to indicate the address of the laboratory location in 22,749 reports for routine chemistry tests and 2,946 reports for urinalysis tests results that were reported by the laboratory from January 1, 2018 to December 31, 2018. Refer to D 5805. 3. The testing personnel confirmed on March 13, 2019 at 12:38 PM, that the laboratory did not have the written protocol to assess the test reports information since January 2017.
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 Puerto Rico Proficiency Testing Program (P.R. PTP) records(years 2017 and 2018), Bio-Rad controls materials package insert, laboratory freezer temperature chart records (years 2018 and 2019), routine chemistry quality control records (years 2016, 2017 and 2018), Coulter LH 500 system manufacturer' instructions, Scal calibrator material package insert, calibration records (years 2017 and 2018) review for the Coulter LH 500 system, pregnancy tests testing records (years 2017, 2018 and 2019), QA program, QA assessment records review (years 2017, 2018 and 2019), interview with the laboratory director and testing personnel on March 13, 2019 at 12: 38 PM, it was determined that the laboratory director failed to fulfill her responsibilities and duties to ensure compliance with the P.R. PTP records retention, P. R. PTP corrective action, laboratory analytical system and quality assessment requirements. The findings include: 1. Refer to D 6079 (The laboratory director failed to comply with the laboratory retention requirements for P.R. PT P records). 2. Refer to D 6092 (The laboratory director failed to follow a corrective action plan when the laboratory obtained unsatisfactory results in hematology specialties). 3. Refer to D 6093 (The laboratory director failed to comply with the requirements for analytic systems from January 2017 to March 2019). 4. Refer to D 6094 (The laboratory director failed to comply with the quality assessment QA requirements).
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on Puerto Rico Proficiency Testing Program (P.R. PTP) records(years 2017 and 2018) review and testing personnel interview on March 13, 2019 at 12:30 PM, it was determined that the laboratory director failed to comply with the laboratory retention requirements for P.R. PT P records . Refer D 3037.
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 Program (P.R. PTP) records(years 2017 and 2018) review and testing personnel interview on March 13, 2019 at 12:20 PM, it

	was determined that the laboratory director failed to follow a corrective action plan when the laboratory obtained unsatisfactory results in hematology specialties. The finding include: 1. Refer to D 2028 (The laboratory obtained unsatisfactory results of 60 percent for white blood cell count in the second event (July 2018). No remedial actions were taken).
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 Bio-Rad controls materials package insert, laboratory freezer temperature chart records (years 2018 and 2019), routine chemistry quality control records (years 2016, 2017 and 2018), Coulter LH 500 system manufacturer' instructions, Scal calibrator material package insert, calibration records (years 2017 and 2018) review for the Coulter LH 500 system, pregnancy tests testing records (years 2017, 2018 and 2019) review and interview with the testing personnel on March 13, 2019 at 11:40 AM, it was determined that laboratory director failed to comply with the requirements for analytic systems from January 2017 to March 2019. Refer to D 5016 (The laboratory failed to ensure compliance with the analytic system requirements for routine chemistry from January 2017 to March 2019). Refer to D 5024 (The laboratory failed to ensure compliance with the analytic system requirements for CBC tests). Refer to D 5449 (The laboratory failed to include at least once a day a negative and a positive control materials when two out of two patients specimens were tested and reported from July 28, 2017 to December 27, 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 QA program, QA assessment records review (years 2017, 2018 and 2019) and interview with the laboratory director on March 13, 2019 at 12:38 PM, it was determined that laboratory director failed to comply with the quality assessment QA requirements. The findings include: 1. Refer to D 5791 (The laboratory did not have a written procedures to monitor and evaluate the patient tests results for inconsistencies with the patient information since January 2017). 2. Refer to D 5891 (The laboratory did not have written protocol to monitor the test reports information since January 2017).
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: Based on Bio-Rad controls materials package insert, laboratory freezer temperature chart records (years 2018 and 2019), routine chemistry quality control records (years 2016, 2017 and 2018), Coulter LH 500 system manufacturer' instructions, Scal calibrator material package insert, calibration records (years 2017 and 2018) review for the Coulter LH 500 system, pregnancy tests testing records (years 2017, 2018 and 2019) review and interview with the testing personnel on March 13, 2019 at 11:40 AM, it was determined that testing personnel failed to fulfill the testing personnel responsibilities from January 2017 to March 2019. Refer to D 6177.
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 Bio-Rad controls materials package insert, laboratory freezer temperature chart records (years 2018 and 2019), routine chemistry quality control records (years 2016, 2017 and 2018), Coulter LH 500 system manufacturer' instructions, Scal calibrator material package insert, calibration records (years 2017 and 2018) review for the Coulter LH 500 system, pregnancy tests testing records (years 2017, 2018 and 2019) review and interview with the testing personnel on March 13, 2019 at 11:40 AM, it was determined that testing personnel failed to follow quality control procedures from January 2017 to March 2019. Refer to D 5016 (The laboratory failed to ensure compliance with the analytic system requirements for routine chemistry from January 2017 to March 2019). Refer to D 5024 (The laboratory failed to ensure compliance with the analytic system requirements for CBC tests). Refer to D 5449 (The laboratory failed to include at least once a day a negative and a positive control materials when two out of two patients specimens were tested and reported from July 28, 2017 to December 27, 2018).