Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0669861	11/15/2022
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Dr Agustin Stahl	Carr 174 Bloque 21 No 2o Sta Rosa, Bayamon, 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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on Puerto Rico Proficiency Testing Program (PRPTP) records review (2022) and laboratory testing personnel interview on November 15, 2022 at 8:45 A.M. , it was determined that the laboratory director failed to sign the attestation statements. The findings include: a. Puerto Rico Proficiency testing records were review from September 2022 to October 2022. (review on November 15, 2022 at 8:50 a.m.) b. The review of records showed that the laboratory director did not sign the attestation statements of the Proficiency testing records from September 2022 to October 2022. (review on November 15, 2022 at 8:53 a.m.) c. The laboratory testing personnel confirmed on November 15, 2022 at 8:55 A.M. that the laboratory director failed to sign the attestation statements.
D3039	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(5) Quality system assessment records. Retain all laboratory quality system assessment records for at least 2 years. This STANDARD is not met as evidenced by: Based on lack of Quality Assessment (QA) records(year 2021-2022) and laboratory testing personnel interview on November 15, 2022 at 9:00A.M., it was found that the laboratory did not retain nor perform the evaluations of the Quality Assessment

	Program in order to monitor and evaluate the laboratory activities (general laboratory system, pre-analytic, analytic and post-analytic systems). The findings include: a. The laboratory did not have any document related to the QA program for year 2021-2022. No Q.A. procedure manual was found at the facility. b. During interview on November 15, 2022 at 9:15 a.m. with the laboratory testing personnel, the QA program evaluation were requested. The laboratory testing personnel stated that the laboratory did not have available the Quality Assessment documentation in the laboratory.
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 lack of Quality Assessment (QA) activities records review (year 2021-2022) and laboratory testing personnel interview on November 15, 2022 at 9:00 A.M., it was determined that laboratory failed to evaluate and monitor the General Laboratory system requirements . The findings include: a. On November 15, 2022 at 9:00 AM, the laboratory QA activities, since the last regular survey (february 23, 2021) were requested. No QA record was available. b. The laboratory did not have any evaluations related to: Patient confidentiality, specimen identification and integrity, compliant investigation, communications and personnel competency. c. The laboratory testing personnel confirmed on November 15, 2022 at 9:10 A.M. that the QA 2021-2022 were not available in the laboratory.
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 lack of Quality Assessment (QA) records (year 2021-2022) and laboratory testing personnel interview on November 15, 2022 at 9:00 A.M. , it was determined that the laboratory failed to evaluate Quality Assessment Program and monitor the requirement for pre-analytic systems. The findings include: a. On November 15, 2022 at 9:10 AM, the laboratory QA activities, since the last regular survey (February 23, 2021) were requested. No QA record was available. No QA records was available. b. The laboratory did not have any evaluations related to: test request, specimen submission and handling, specimen referral. c. The laboratory testing personnel confirmed on November 15, 2022 at 9:15 A.M. that the QA 2021-2022 were not available in the laboratory.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250

	Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of hematology, syphilis serology and endocrinology quality control records review (year 2021-2022) and interview with the laboratory testing personnel (MT-600) on November 15, 2022 at 1:00p.m. , it was dtermined that the laboratoty failed to meet requirements for analytic systems. Refer to D5413- the laboratory failed to monitor and document the laboratory's room temperature, relative humidity, refrigerator and freezer temperatures. D5417- the laboratory performed human chorionic gonadotropin (hCG) test with reagent that exceeded the expiration date. D5429- the laboratory failed to perform and document the preventive maintenance of microscope each day of use. D5437- the laboratory failed to perform the calibration verification procedures with at least the frequency recommended by the manufacturer's (each six months) for the hematology tests performed by the Cell Dyn 1700 system. D5449- the laboratory failed to include a negative and a positive control material when performed hCG test. D5469- the laboratory did not evaluated nor established the statically values for the streck control material used by the laboratory since February 2022. D5471- the laboratory did not evaluate the new lot of syphilis serology test (Rapid Plasma reagin method) for positive and negative reactivity prior to placed it in routine use. D5783-the laboratory did not evaluate the hematology QC graphs since February 2022. D5787-the laboratory test results did not include the signature of the testing personnel authorized to perform the test.
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 preventive maintenance log sheets review (year 2021-2022) and laboratory testing personnel interview on November 15, 2022 at 12:27 p.m., it was determined that the laboratory failed to monitor and document the laboratory's room temperature, relative humidity, refrigerator and freezer temperatures. The findings include: a. The laboratory log sheets establishes that the laboratory must monitor and document daily the room temperature, relative humidity, refrigerator and freezer temperatures. b. Since November 4, 2022, the laboratory did not monitor and document daily the refrigerator and freezer temperatures. c. Since November 9, 2022, the laboratory did not monitor and document daily the room temperature and relative humidity, d. The laboratory testing personnel confirmed on November 15, 2022 at 12: 35 p.m. that the laboratory did not monitor and document the room temperature,

	relative humidity since November 4, 2022 and did not monitor and document the refrigerator and freezer temperatures since November 9, 2022.
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 review of the laboratory hCG patient and quality control worksheet on laboratory and laboratory testing personnel interview on November 15, 2022 at 12:18 p.m. , it was determined that the laboratory performed human chorionic gonadotropin (hCG) test with reagent that exceeded the expiration date. The findings include: a. The laboratory performed serum human chorionic gonadotropin (hCG) test. b. Review of the laboratory hCG worksheet showed that the laboratory had in use the hCG reagent lot : F2009025, exp. date : 08/2022 from 9/2022 to 10/2022. (review on November 15, 2022 at 12:20 p.m.) c. The laboratory processed and reported 11 hCG patient and proficiency samples with the expired reagent kit during the following days: date patient identification 9/21/2022 601042 9/28/2022 602452 10/1/2022 602872 10/10/2022 604132 10/11/2022 604272 10/14/2022 PT-801-805 10/22/2022 606472 d. The laboratory testing personnel confirmed on November 15, 2022 at 12:22 p.m. that the the laboratory performed hCG test with reagent that exceeded the expiration date.
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 preventive maintenance log sheets review (year 2022) and laboratory testing personnel interview on November 15, 2022 at 12:40 P.M. it was determined that the laboratory failed to perform and document the preventive maintenance of microscope each day of use. The findings include: a. Review of the microscope preventive maintenance manual log , showed that the laboratory must document the cleaning of the microscope each day of use. (review on November 15, 2022 at 12: 40 p.m.) b. On November 15, 2022 at 12:42 p.m. it was observed that no preventive maintenance was documented since November 9, 2022. c. The testing personnel confirmed on November 15, 2022 at 12:45 P.M. , that this preventive maintenance was not perform nor document since November 9, 2022.
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 hematology calibration records reviewed (years 2021-2022) and laboratory testing personnel interview on November 15, 2022 at 9: 10 AM, it was determined that the laboratory failed to perform the calibration verification procedures with at least the frequency recommended by the manufacturer's (each six months) for the hematology tests performed by the Cell Dyn 1700 system. The findings include: a. The laboratory uses a Cell Dyn 1700 system for CBC (Complete blood count) patient's tests. b. The manufacturer's instructions establishes that the laboratory must perform the calibration verification procedures each six months. (review on November 15, 2022 at 9:12 a.m.) c. The records showed that the laboratory did not perform the calibration verification procedures during April 2021, October 2021 nor April 2022. (review November 15, 2022 at 9:14 a.m.) d. The laboratory performed and reported 5,750 hematology tests in 2021. (review November 15, 2022 at 9:14 a. m.) e. The laboratory testing personnel confirmed on November 15, 2022 at 9: 15 a. m. that the laboratory did not perform at least every 6 months the calibration verification procedures for the Cell Dyn 1700 system.
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 observation and laboratory testing personnel interview on November 15, 2022 at 12:18 p.m. , it was determined that the laboratory failed to include a negative and a positive control material when performed serum hCG patient's test. The findings include : a The laboratory performed serum hCG (human chorionic gonadotropin) by one step method. b Endocrinology quality control logs were reviewed from January /2022 to November 15, 2022. (reviewed on November 15, 2022 at 12:18 p.m.) c. The records showed that the laboratory did not include a negative and a positive control material from September 2022 to October 22, 2022. (review on November 15, 2022 at 12:18 p.m.) d. The laboratory processed and reported 11 serum hCG patient and proficiency samples the following days: date patient identification 9/21/2022 601042 9 /28/2022 602452 10/1/2022 602872 10/10/2022 604132 10/11/2022 604272 10/14 /2022 PT-801-805 10/22/2022 606472 e. The laboratory testing personnel confirmed on November 15, 2022 at 12:25 p.m. that the laboratory failed to include a negative and a positive control material when performed serum hCG patient's test.
D5469	CONTROL PROCEDURES

	CFR(s): 493.1256(d)(10)(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--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on manufacturer's stated hematology assay values, printout and laboratory testing personnel interview on November 15, 2022 at 10:49 a.m. , it was determined that the laboratory did not evaluated nor established the statically values for the streck control material used by the laboratory since February 2022. The findings include: a. The laboratory used the Cell Dyn 1700 instrument to perform patient testing. b. The streck control material showed that the assayed values are for the Cell Dyn 1800 instrument, not for the Cell Dyn 1700. (review on November 15, 2022 at 10:52 a.m.) c. During the survey the evaluation of the unassayed control material was requested. (review on November 15, 2022 at 10:55 a.m.) d. The testing personnel stated that no evaluations of the control material were performed, however, the control material was in used since February 2022. (review on November 15, 2022 at 10:56 a.m.) e. The laboratory performed and reported 536 hematology patient' s samples from February to April 2022. (review on November 15, 2022 at 11:00 a.m.)
D5471	CONTROL PROCEDURES CFR(s): 493.1256(e)(1)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on syphilis serology quality control records review (years 2021-2022) and laboratory testing personnel interview at 11:52 AM on November 15, 2022, it was determined that the laboratory did not evaluate the new lot of Rapid Plasma reagin (RPR) test for positive and negative reactivity prior to placed it in routine use. The findings include: a. The laboratory quality control records were review from January 2022 to November 15, 2022. (reviwed on November 15, 2022 at 11:54 a.m.) b. The laboratory received the following reagent kit for syphilis serology test (RPR Method) and no evaluation of their reactivity was performed: Test Lot Expiration Date RPR 21121612 12/31/2023 c. The laboratory testing personnel confirmed on November 15,

	2022 at 11:55 a.m. that the laboratory did not evaluate the new lot of Rapid Plasma reagin (RPR) test for positive and negative reactivity prior to placed it in routine use.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on Levy Jennings hematology quality control graphs and interview with the laboratory testing personnel on November 15, 2022 at 10:00 a.m., it was determined that the laboratory did not evaluate the hematology QC graphs since February 2022. The findings include: a. Review of the Levy Jennings graphs, since February 2022 , showed that for the three levels control material the laboratory established a bracket value of 99.8 to 0.0 with a 49.9 mean value. (review on November 15, 2022 at 10:00 a.m.) b. The laboratory did not evaluate the daily quality control values in order to determine of shifts, trends or outliers occurred during the daily run. (review on November 15, 2022 at 10:04 a.m.) c. The laboratory testing personnal confirmed on November 15, 2022 at 10:06 a.m. , that the laboratory did not evaluate the hematology QC graphs since February 2022.
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: Based on testing records review and interview with the laboratory testing personnel on November 15, 2022 at 10:00 a.m. , it was determined that the laboratory test results did not include the signature of the testing personnel authorized to perform the test. The findings include: a. The testing records showed that the laboratory did not include the signature of the personnel authorized to perform the test of the patients specimen since September 2022. (reviewed at 10:05 a.m.) b. On November 14, 2022 at 10:05 a. m.patient testing records were reviewed (4 complete blood count- CBC and 6 Urinalysis test). These results included the laboratory director sign as the testing personnel who performed and reported the test results. c. The testing personnel (MT-600) stated on November 15, 2022 at 10:10 a.m that since September 2022 she was recruited as Medical Technologist to performed patient tests, however, the laboratory failed to include in the laboratory information system (LIS) the electronic sign of the new testing personnel.

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 lack of Quality Assessment (QA) records (year 2021-2022) and laboratory testing personnel interview on November 15, 2022 at 9:00 A.M., it was determined that the laboratory failed to have available a Quality Assessment Program to monitor and evaluate the following requirements for postanalytic systems: turn around time and the patient's final test reports. The findings include: a. On November 15, 2022 at 9: 10 AM,the laboratory QA activities, since the last regular survey (February 23, 2021) were requested. No QA record was available. No QA records was available. (Review on November 15, 2022 at 9:04 a.m.) b. The laboratory did not have any evaluations related to: turn around time and the patient's final test reports.(Review on November 15, 2022 at 9:05 a.m.) c. The laboratory testing personnel confirmed on November 15, 2022 at 9:20 A.M. that the QA 2021-2022 were not available in the laboratory.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on hematology , syphilis serology and endocrinology quality control records review (year 2021-2022) and laboratory testing personnel interview on November 15, 2022 at 1:00 P.M. April 16, 2021 at 12:30 P.M. it was determined that the laboratory director failed to fulfill his responsibilities and duties to ensure compliance with the laboratory analytical system requirements. The finding includes: 1. The laboratory director did not comply with the requirement for analytical systems requirements. Refer to D 6020.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on hematology, syphilis serology and endocrinology quality control records review (year 2021-2022) and interview with the laboratory testing personnel (MT-

	600) on November 15, 2022 at 1:00 p.m , it was determined that laboratory director failed to ensure compliance with the requirements for analytic systems. Refer to D 5413- the laboratory failed to monitor and document the laboratory's room temperature, relative humidity, refrigerator and freezer temperatures. D5417- the laboratory performed human chorionic gonadotropin (hCG) test with reagent that exceeded the expiration date. D5429- the laboratory failed to perform and document the preventive maintenance of microscope each day of use. D5437- the laboratory failed to perform the calibration verification procedures with at least the frequency recommended by the manufacturer's (each six months) for the hematology tests performed by the Cell Dyn 1700 system. D5449- the laboratory failed to include a negative and a positive control material when performed hCG test. D5469- the laboratory did not evaluated nor established the statically values for the streck control material used by the laboratory since February 2022. D5471- the laboratory did not evaluate the new lot of syphilis serology test (Rapid Plasma reagin method) for positive and negative reactivity prior to placed it in routine use. D5783-the laboratory did not evaluate the hematology QC graphs since February 2022. D5787-the laboratory test results did not include the signature of the testing personnel authorized to perform the test.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on lack of Quality Assessment (QA) records (year 2021-2022) and laboratory testing personnel interview on November 15, 2022 at 1:15 p.m., it was determined that laboratory director failed to ensure compliance with quality assessment requirements. Refer to D5291, D5391 and D5891.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on personnel records review and laboratory testing personnel interview on November 15, 2022 at 9:35 a.m., it was determined that the laboratory director did not make sure that the new testing personnel (MT-600), had the necessary training

	before beginning to perform patient tests from September 2022 to November 15, 2022. The findings include: a. The new testing personnel (MT -600) was hired and performed patient testing since September 2022. (review on November 15, 2022 at 9: 37 a.m.) b. The laboratory did not have any document related to testing personnel training. However, this testing personnel processed and reported patient's specimens in the following laboratory's areas: hematology, urinalysis, endocrinology , syphilis and covid testing. (review on November 15, 2022 at 9:38 a.m.)
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) 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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on personnel records review and laboratory testing personal (MT-600) interview on November 15, 2022 at 9:35 a.m. . it was determined that the laboratory director failed to fulfill her responsibilities to ensure that the new testing personnel is competent to perform laboratory test procedures from September 2022 to November 15, 2022. The findings include: a. The new testing personnel (MT-600) was hired and performed patient's testing since September 2022. (review on November 15, 2022 at 9:37 a.m.) b. The new testing personnel processed and reported patient's specimens in the following laboratory's areas from September 2022 to November 15, 2022 : hematology, urinalysis, endocrinology, syphilis and covid testing. (review on November 15, 2022 at 9:37 a.m.) c. The laboratory testing personnel (MT-600) confirmed on November 15, 2022 at 9:39 a.m. , that the laboratory director did not perform nor document the testing personnel competence since September 2022.
D6072	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(3) Each individual performing moderate 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 hematology, syphilis serology and endocrinology quality control records review (year 2021-2022) and interview with the laboratory testing personnel (MT-600) on November 15, 2022 at 1:00 p.m , it was determined that laboratory testing personnel failed to ensure compliance with the requirements for analytic systems. Refer to D 5413- the laboratory failed to monitor and document the laboratory's room temperature, relative humidity, refrigerator and freezer temperatures. D5417- the laboratory performed human chorionic gonadotropin (hCG) test with reagent that

	exceeded the expiration date. D5429- the laboratory failed to perform and document the preventive maintenance of microscope each day of use. D5437- the laboratory failed to perform the calibration verification procedures with at least the frequency recommended by the manufacturer's (each six months) for the hematology tests performed by the Cell Dyn 1700 system. D5449- the laboratory failed to include a negative and a positive control material when performed hCG test. D5469- the laboratory did not evaluated nor established the statically values for the streck control material used by the laboratory since February 2022. D5471- the laboratory did not evaluate the new lot of syphilis serology test (Rapid Plasma reagin method) for positive and negative reactivity prior to placed it in routine use. D5783-the laboratory did not evaluate the hematology QC graphs since February 2022. D5787-the laboratory test results did not include the signature of the testing personnel authorized to perform the test.