Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0677191	07/19/2018
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Alhambra	Calle Comercio #104, Juana Diaz, 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
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, laboratory quality control records review in years 2016-2018 and laboratory general supervisor interview on July 19, 2018 at 1:00 PM, it was determined that the laboratory failed to monitor and document the laboratory's relative humidity. The findings include: 1. The laboratory procedures manual establishes that the laboratory monitor and document daily the relative humidity (45-65%). 2. From August 1, 2016 to July 19, 2018, the records showed that the laboratory did not monitor and document the daily relative humidity since January 2017. 3. The laboratory general supervisor confirmed on July 19, 2018, that the laboratory did not monitor and document the relative humidity since January 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: A. Based on manufacturer's instructions, endocrinology quality control records review in years 2016-2018 and laboratory general supervisor interview on July 19, 2018 at 1: 00 PM, it was determined that the laboratory failed to include each day of testing the positive and the negative control materials when patients samples were tested for qualitative Human Chorionic Gonadotropin (HCG) by OSOM method. The findings include: 1. The laboratory uses Human Chorionic Gonadotropin (HCG) by OSOM method. 2. The manufacturer's establishes to include each day of testing one negative and one positive material control. 2. From October 2016 to July 2018, the records showed that the laboratory failed to include at least once a day, a negative nor positive control material when 2 of 2 patients specimens were processed and reported for qualitative HcG patient's samples in the following days: Date # samples 2/9/18 1 2/28 /18 1 3. The laboratory processed and reported two (2) HcG patient's samples on February 9, 2018 and February 28, 2018, respectively. 4. The laboratory general supervisor confirmed on July 19, 2018 that the laboratory failed to include each day of testing the positive and the negative control materials when patient's sample's were tested for qualitative Human Chorionic Gonadotropin (HCG) by OSOM method those days. B. Based on manufacturer's instructions, endocrinology quality control records review in years 2016-2018 and laboratory general supervisor interview on July 19, 2018 at 1:00 PM, it was determined that the laboratory failed to verify the validity of each kit when material control and HcG patients samples were tested for qualitative Human Chorionic Gonadotropin (HCG) by OSOM method. The findings include: 1. The laboratory uses Human Chorionic Gonadotropin (HCG) by OSOM method. 2. The manufacturer's establishes to verify the validity of each HcG kit, monitor and evaluate the control line does appears. (Invalid kit means that the control line does not appear). 2. From October 2016 to July 2018, the records showed that the laboratory failed to evaluate nor document the validity of each kit when HcG patients samples were processed and reported in the following days: Date # samples 2/9/18 1 2/28/18 1 3. The laboratory processed and reported two (2) HcG patient's samples on February 9, 2018 and February 28, 2018, respectively. 4. The laboratory general supervisor confirmed on July 19, 2018 that the laboratory failed to verify the validity of each kit when material control and patients samples were tested for qualitative Human Chorionic Gonadotropin (HCG) by OSOM method.
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: A. Based on laboratory procedure manual, routine chemistry quality control review in years 2016-2018 and laboratory general supervisor interview at 1:00 PM, it was determined that the laboratory failed to evaluate the quality control results for routine chemistry tests processed by the Vitro 250 system. The findings include: 1. The laboratory uses a Vitros 250 system to perform routine chemistry patient's samples tests for Albumin, ALP (Alkaline phosphate), ALT (Alanine Aminotransferase), AMY (Amylase), AST (Aspartate Aminotrasferase), T. Bili (Total Bilirubin), BUN (Urea Nitrogen) and Calcium. 2. The laboratory uses two material controls for each test. (verify I and verify II). 3.. The laboratory establishes to evaluate in Levy-Jenninsg graphs control results each month. 4. Review of routine chemistry quality control records from October 2016 to June 2018, showed that the laboratory performed quality control procedures, however, did not evaluate in Levy-Jennings graphs the quality control results in the following dates: Test Date Control Level Albumin 2/6/18 Verify II 3/15/18 Verify I 5/23/18 Verify II 6/1/18 Verify II ALP 2/15 /18 Verify II 3/13/18 Verify I 5/23/18 Verity II 6/8/18 Verify I 6/16/18 Verify I ALT 3 /15/18 Verify I 4/26/18 Verify II 5/9/18 Verify I AMY 3/6/18 Verify I AST 1/22/18 Verify II 3/15/18 Verify I 5/23/18 Verify II T. Bili 3/15/18 Verify I 6/11/18 Verify I 6 /12/18 Verify I Bun 3/15/18 Verify I Calcium 3/15/18 Verify I 5. The laboratory reported and processed aproximately One hundred (100) patient's samples during those days. 6. The laboratory general supervisor confirmed on July 19, 2018 that the laboratory did not evaluate in Levy-Jennings graphs the quality control results those days. B. Based on laboratory procedure manual, special chemistry quality control review in years 2016-2018 and laboratory general supervisor interview at 1:00 PM, it was determined that the laboratory failed to evaluate the quality control results for routine chemistry tests processed by the Elecsys 2010 system. The findings include: 1. The laboratory uses a Elecsys 2010 system to perform special chemistry patient's samples tests for FT4 (Free Thyroxine), TSH (Thyroid Stimulating hormone, (PSA (Prostate specific antigen, T4 (Thyroxine), Vit D (Vitamin D, 25OH) and Vit. B12 (Vitamin B12) 2. The laboratory uses three material controls for each test. (V-0, V-1, V-2). 3.. The laboratory establishes to evaluate in Levy-Jenninsg graphs control results each month. 4. Review of special chemistry quality control records from October 2016 to June 2018, showed that the laboratory performed quality control procedures, however, did not evaluate in Levy-Jennings graphs the quality control results in the following dates: Test Date Control Level TSH 1/18/18 V-2 3/27/18 V-2 4 /20/18 V-2 FT4 1/22/18 V-2 1/23/18 V-2 1/25/18 V-1 1/26/18 V-2 2/2/18 V-2 2/23/18 V-2 PSA 2/2/18 V-2 2/14/18 V-2 2/23/18 V-2 3/27/18 V-2 4/20/18 V-2 5/9/18 V-1 5 /10/18 V-2 T4 1/8/18 V-2 3/27/18 V-2 4/20/18 V-2 5/16/18 V-1 Vit D 2/22/18 V-1 3/9 /18 V-1 5/10/18 V-1, V-2 Vit B12 12/20/17 V-0 4/19/18 V-0, V-2 5/10/18 V-0, V-2 5. The laboratory reported and processed aproximately Thirty (30) patient's samples during those days. 6. The laboratory general supervisor confirmed on July 19, 2018 that the laboratory did not evaluate in Levy-Jennings graphs the quality control results those days.
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 control records review in years 2016-2017 and laboratory general supervisor interview on July 19, 2018 at 1:00 PM, it was determined that the laboratory failed to follow the established Quality Assessment Program to monitor and evaluate the requirements for analytic system. The findings include: 1. The laboratory failed to monitor and document the laboratory's room relative humidity. Refer D5413 2. The laboratory failed to include each day of testing the positive and the negative control materials when patient's specimens were tested for qualitative Human Chorionic Gonadotropin (HCG) by OSOM method. Refer D5449. 3. The laboratory failed to evaluate the quality control results for routine chemistry tests processed by the Vitro 250 system. Refer D5469.
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 assesment (QA) records review in years 2016-2018 and laboratory general supervisor interview on July 19, 2018 at 1:00 PM, it was determined that the laboratory failed to monitor problems identified in the post analytical systems (turn around time) . The finding includes: 1. The laboratory Quality Assessment records schedule for turn around time evaluation showed that it must be performed every year. 2. The laboratory did not perform any evaluation to the post analytic system since January 2016. 3. The laboratory general supervisor confirmed on July 19, 2018 that the laboratory failed to monitor problems identified in the post analytical systems (turn around time)
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 laboratory procedure manual, quality control records review in years 2016-2018 and laboratory general supervisor interview at 1:00 PM on July 19, 2018, it was determined that the laboratory failed to ensure compliance with the requirements for analytic systems. Refer to D5413, D5449 and D5469.
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 records review in years 2016-2018 and laboratory general supervisor interview at 1:00 PM on July 19, 2018, it was determined that the laboratory failed to ensure compliance with quality assessment (QA) requirements. Refer to D5791 and D5891.
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 laboratory procedure manual, quality control records review in years 2016-2018 and laboratory general supervisor interview at 1:00 PM on July 19, 2018, it was determined that the general supervisor failed to follow quality control procedures. The findings include: 1. The laboratory failed to monitor and document the laboratory's room relative humidity. Refer D5413 2. The laboratory failed to include each day of testing the positive and the negative control materials when patient's specimens were tested for qualitative Human Chorionic Gonadotropin (HCG) by OSOM method. Refer D5449. 3. The laboratory failed to evaluate the quality control results for routine chemistry tests processed by the Vitro 250 system. Refer D5469.
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 laboratory procedure manual, quality control records review in years 2016-2018 and laboratory general supervisor interview at 1:00 PM on July 19, 2018, it was determined that testing personnel failed to follow quality control procedures. The findings include: 1. The laboratory failed to monitor and document the laboratory's room relative humidity. Refer D5413 2. The laboratory failed to include each day of testing the positive and the negative control materials when patient's specimens were tested for qualitative Human Chorionic Gonadotropin (HCG) by OSOM method. Refer D5449. 3. The laboratory failed to evaluate the quality control results for routine chemistry tests processed by the Vitro 250 system. Refer D5469.