Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0963614	08/15/2018
Name of Provider or Supplier	**Street Address, City, State**	
Laboratoro Clinico C& C, Csp	Centro Comercial Barinas Local 10, Carr 335, Yauco, 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
D5002	BACTERIOLOGY CFR(s): 493.1201 If the laboratory provides services in the subspecialty of Bacteriology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1261, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on bacteriology media quality control records (from 8/15/2016 to 8/15/2018), Microscan susceptibility tests quality control records (from 8/15/2016 to 8/15/2018), annual volume records (years 2016, 2017 and 2018) and general supervisor interview on August 15, 2018 at 9:45 AM, it was determined that the laboratory failed to meet the analytic requirements of Bacteriology subspecialty from 8/15/2016 to 8/15/2018. Refer to D 5477 (The laboratory failed to check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response). Refer to D 5507 (The laboratory failed to check each day of testing the susceptibility tests from 8/15/2016 to 8/15/2018).
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 Sysmex CA 500 system print-out records (years 2017- 2018), Prothrombin time (PT) and Partial Thrombin time (PTT) testing records (years 2017- 2018) , PT

	and PTT quality control records (years 2017 - 2018) review and general supervisor interview on August 15, 2018 at 11:28 AM, it was determined that the laboratory failed to meet the analytic requirement for PT and PTT when 6 out of 6 patients specimens were tested from April 19, 2017 to June 18, 2018. Refer to D 5545 (The laboratory failed to include two levels of control material each 8 hours of operation when 6 out of 6 patients specimens were tested from April 19, 2017 to June 18, 2018).
D5451	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(iii)(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-- Test procedures producing graded or titered results include a negative control material and a control material with graded or titered reactivity, respectively; 493.1256 (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on C reactive protein (CRP) quantitative tests testing (years 2017 to 2018) records review and general supervisor interview on August 15, 2018 at 11:25 AM, it was determined that the laboratory failed to include a negative control material besides the a control material with tittered reactivity, when 7 out of 7 patients specimens were tested and reported for CRP quantitative tests from July 11, 2018 to July 19, 2018. The findings include: 1. The laboratory performed qualitative and quantitative tests. 2. On August 15, 2018 at 11:25 AM, the CRP quantitative tests testing records showed that the laboratory did not include a negative control material besides the a control material with tittered reactivity, when the 7 out of 7 patients specimens were tested and reported for CRP quantitative tests from July 11, 2018 to July 19, 2018: Date Patients processed ID July 11, 2018 35856/ 4822 July 12, 2018 35938/ 2119 July 13, 2018 35998/ 12671 July 14, 2018 36088/ 3349 July 14, 2018 36229/ 6353 July 17, 2018 36252/ 11327 July 19, 2018 36353/ 9228 3. The general supervisor confirmed on August 15, 2018 at 11:30 AM, that the CRP testing records did not include the negative control requirement. He stated that the laboratory included the negative control those days but not recorded.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on bacteriology media quality control records (from 8/15/2016 to 8/15/2018), annual volume records (years 2016, 2017 and 2018) and general supervisor interview on August 15, 2018 at 9:45 AM, it was determined that the laboratory failed to check each batch of media for its ability to support growth and, as appropriate, select or

	inhibit specific organisms or produce a biochemical response from 8/15/2016 to 8/15 /2018. The findings include: 1. On August 15, 2018 at 9:45 AM, the bacteriology media quality control records showed that the laboratory did not check each batch of media (blood agar, Mac Coney agar, Mac Coney orbiter, LD, monitol agar, selenite and hagiolatry agar) for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response from 8/15/2016 to 8/15 /2018. 2. The general supervisor confirmed on August 15, 2018 at 9:45 AM, that the laboratory did not check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response from 8/15/2016 to 8/15/2018. He stated that the laboratory retained the manufacturer's quality control record. 3. The laboratory annual volume records showed that the laboratory processed the following patients cultures specimens: Years patients cultures specimens 2016 1,608 cultures 2017 2, 278 cultures 2018 1,786 cultures
D5507	BACTERIOLOGY CFR(s): 493.1261(b)(c) (b) For antimicrobial susceptibility tests, the laboratory must check each batch of media and each lot number and shipment of antimicrobial agent(s) before, or concurrent with, initial use, using approved control organisms. (b)(1) Each day tests are performed, the laboratory must use the appropriate control organism(s) to check the procedure. (b)(2) The laboratory's zone sizes or minimum inhibitory concentration for control organisms must be within established limits before reporting patient results. (c) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on Microscan susceptibility tests quality control records (from 8/15/2016 to 8 /15/2018), annual volume records (years 2016, 2017 and 2018) and general supervisor interview on August 15, 2018 at 9:30 AM, it was determined that the laboratory failed to check each day of testing the susceptibility tests from 8/15/2016 to 8/15/2018. The finding include: 1. On August 15, 2018 at 9:30 AM, the Microscan susceptibility tests quality control records showed that the laboratory did not check check each day of testing the susceptibility tests from 8/15/2016 to 8/15/2018. 2. The general supervisor stated that the laboratory performed the susceptibility tests quality control records weekly and monthly. 3. The laboratory annual volume records showed that the laboratory processed the following patients cultures specimens: Years patients cultures specimens 2016 1,608 cultures 2017 2, 278 cultures 2018 1,786 cultures
D5545	HEMATOLOGY CFR(s): 493.1269(b)(d) (b) For all nonmanual coagulation test systems, the laboratory must include two levels of control material each 8 hours of operation and each time a reagent is changed. (d) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on Sysmex CA 500 system print-out records (years 2017- 2018), Prothrombin time (PT) and Partial Thrombin time (PTT) testing records (years 2017- 2018) , PT and PTT quality control records (years 2017 - 2018) review and general supervisor

	interview on August 15, 2018 at 11:28 AM, it was determined that the laboratory failed to include two levels of control material each 8 hours of operation when 6 out of 6 patients specimens were tested from April 19, 2017 to June 18, 2018. The findings include: 1. The laboratory processed the PT and PTT tests by the Sysmex CA 500 system from April 19, 2017 to June 18, 2018. 2. The Sysmex CA 500 system print-out records showed that the laboratory did not include two levels of control material each 8 hours of operation when 6 out of 6 patients specimens for PT and PTT tests were processed and reported by the Sysmex CA 500 system from April 19, 2017 to June 18, 2018: Date of patient time control time patients PT/PTT testing ID processing processing April 19, 2017 910166 6:43 AM 4:23 PM April 19, 2018 30904- 6:51 AM 3:53 PM 9117 April 25, 2018 31286- 6:45 AM 3:29 PM 3100 June 11, 2018 34188- 6:44 AM 4:27 PM 611 June 18, 2018 34627- 6:43 AM 4:31 PM 1231 June 18, 2018 34627- 6:43 AM 4:19 PM 1232 3. The general supervisor confirmed that the PT and PTT print out records showed that the laboratory failed to include two levels of control material each 8 hours of operation when those patients specimens were tested and reported for PT and PTT tests.
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 bacteriology media quality control records (from 8/15/2016 to 8/15/2018), Microscan susceptibility tests quality control records (from 8/15/2016 to 8/15/2018), annual volume records (years 2016, 2017 and 2018), Sysmex CA 500 system print-out records (years 2017- 2018), Prothrombin time (PT) and Partial Thrombin time (PTT) testing records (years 2017- 2018) , PT and PTT quality control records (years 2017 - 2018) review and general supervisor interview on August 15, 2018 at 9:45 AM, it was determined that the laboratory director failed to fulfill her responsibilities to ensure that the laboratory comply with the analytic system requirements. Refer to D6093.
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 bacteriology media quality control records (from 8/15/2016 to 8/15/2018), Microscan susceptibility tests quality control records (from 8/15/2016 to 8/15/2018), annual volume records (years 2016, 2017 and 2018), Sysmex CA 500 system print-out records (years 2017- 2018), Prothrombin time (PT) and Partial Thrombin time (PTT) testing records (years 2017- 2018) , PT and PTT quality control records (years 2017 - 2018) review and general supervisor interview on August 15, 2018 at 9:45 AM, it was determined that the laboratory director failed to ensure that the laboratory comply

	with the analytic system requirements. Refer to D 5002 (The laboratory failed to meet the analytic requirements of Bacteriology subspecialty). Refer to D 5024 (The laboratory failed to meet the analytic requirement for PT and PTT tests).
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 bacteriology media quality control records (from 8/15/2016 to 8/15/2018), Microscan susceptibility tests quality control records (from 8/15/2016 to 8/15/2018), annual volume records (years 2016, 2017 and 2018), Sysmex CA 500 system print-out records (years 2017- 2018), Prothrombin time (PT) and Partial Thrombin time (PTT) testing records (years 2017- 2018) , PT and PTT quality control records (years 2017 - 2018) review and general supervisor interview on August 15, 2018 at 9:45 AM, it was determined that the technical supervisor failed to ensure that the laboratory comply with the analytic system requirements. Refer to D 5477 (The laboratory failed to check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response). Refer to D 5507 (The laboratory failed to check each day of testing the susceptibility tests from 8/15 /2016 to 8/15/2018). Refer to D 5545 (The laboratory failed to include two levels of control material each 8 hours of operation when 6 out of 6 patients specimens were tested from April 19, 2017 to June 18, 2018).
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 bacteriology media quality control records (from 8/15/2016 to 8/15/2018), Microscan susceptibility tests quality control records (from 8/15/2016 to 8/15/2018), annual volume records (years 2016, 2017 and 2018), Sysmex CA 500 system print-out records (years 2017- 2018), Prothrombin time (PT) and Partial Thrombin time (PTT) testing records (years 2017- 2018) , PT and PTT quality control records (years 2017 - 2018) review and general supervisor interview on August 15, 2018 at 9:45 AM, it was determined that the general supervisor failed to perform a day-to-day supervision to the personnel performing testing and reporting test results in the bacteriology and coagulation areas. Refer to D 5477 (The laboratory failed to check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response). Refer to D 5507 (The laboratory failed to check each day of testing the susceptibility tests from 8/15/2016 to 8/15 /2018). Refer to D 5545 (The laboratory failed to include two levels of control material each 8 hours of operation when 6 out of 6 patients specimens were tested from April 19, 2017 to June 18, 2018).

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 bacteriology media quality control records (from 8/15/2016 to 8/15/2018), Microscan susceptibility tests quality control records (from 8/15/2016 to 8/15/2018), annual volume records (years 2016, 2017 and 2018), Sysmex CA 500 system print-out records (years 2017- 2018), Prothrombin time (PT) and Partial Thrombin time (PTT) testing records (years 2017- 2018) , PT and PTT quality control records (years 2017 - 2018) review and general supervisor interview on August 15, 2018 at 9:45 AM, it was determined that the testing personnel failed to follow quality control procedures. Refer to D 5477 (The laboratory failed to check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response). Refer to D 5507 (The laboratory failed to check each day of testing the susceptibility tests from 8/15/2016 to 8/15/2018). Refer to D 5545 (The laboratory failed to include two levels of control material each 8 hours of operation when 6 out of 6 patients specimens were tested from April 19, 2017 to June 18, 2018).