

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0673051	(X3) Date Survey Completed 02/27/2019
Name of Provider or Supplier Laboratorio Clinico Cossma Humacao	Street Address, City, State Boulevard Plaza Office Center, Oficina Num 3-A, Humacao, PR	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on Puerto Rico Proficiency Testing Program (P.R.PTP) records (years 2016, 2017 and 2018) review and laboratory general supervisor interview on February 27, 2019 at 9:50 A.M., it was determined that the laboratory failed to enroll in an HHS approved Proficiency Testing Program for Complete blood count (CBC) with white blood cell (WBC) differential with three parameters and failed to test the CBC proficiency testing samples in the same manner as patients' specimens from March 2017 to November 2018. The findings include: 1. Refer to D 2001 (The laboratory failed to enroll in an HHS approved Proficiency Testing Program for the complete blood count (CBC) with the three parameters of white blood cell differential results from March 1, 2017 to August 31, 2017). 2. Refer to D 2010 (The laboratory failed to test the CBC proficiency testing samples the same number of times that it routinely tests patient samples in the March 2017 event). 3. Refer to D 2013 (The Laboratorio Clinico Central I (CLIA 40 D 0673051) processed the proficiency testing samples for CBC of the July 2018 and November 2018 P.R.PT events at Laboratorio Clinico Central II (CLIA 40 D 0952483) and reported the those PT results as its own).</p>

D2001

ENROLLMENT

CFR(s): 493.801(a)(1)(2)(i)

The laboratory must-- (1) Notify HHS of the approved program or programs in which it chooses to participate to meet proficiency testing requirements of this subpart. (2)(i) Designate the program(s) to be used for each specialty, subspecialty, and analyte or test to determine compliance with this subpart if the laboratory participates in more than one proficiency testing program approved by CMS;

This STANDARD is not met as evidenced by:

Based on Puerto Rico Proficiency Testing Program (P.R.PTP) records (years 2017 and 2018) , P.R.PTP test catalog (years 2017 and 2018) review and laboratory general supervisor interview on February 27, 2019 at 9:30 A.M., it was determined that the laboratory failed to enroll in an HHS approved Proficiency Testing Program for CBC tests with three parameters WBC differential since March 1, 2017. The findings includes: 1. The laboratory had a Coulter Act Dif 2 system as their primary tests method. They reported WBC, RBC, Hgb, Hct , platelet and three parameters WBC differential " lymphocytes, granulocytes and mixed". 2. Review of the P.R.PTP test catalog showed that the PT program did not offer any proficiency materials for those laboratories that performed and reported for three parameters WBC differential. 3. On February 27, 2019 at 9:30 A.M., the P.R.PTP records showed that the laboratory was enrolled for WBC, RBC, Hgb, Hct , platelet tests, but with three parameters WBC was not challenged. 4. The laboratory did not enroll in an HHS approved Proficiency Testing Program for the method used by them. 5. The laboratory general supervisor confirmed on February 27, 2019 at 9:30 A.M., the laboratory did not enroll in an HHS approved Proficiency Testing Program for WBC, RBC, Hgb, Hct , platelet tests, but with three parameters WBC differential. She also stated theta she was not aware of the PT requirement. 6. The annual test volume records for the year 2017 showed that the laboratory processed and reported 2,100 out of 2,100 patients specimens for CBC with WBC differential of three parameters.

D2010

TESTING OF PROFICIENCY TESTING SAMPLES

CFR(s): 493.801(b)(2)

The laboratory must test samples the same number of times that it routinely tests patient samples.

This STANDARD is not met as evidenced by:

Based on Puerto Rico Proficiency Testing Program (P.R.PTP) records review (years 2016, 2017 and 2018) and laboratory general supervisor interview on February 27, 2019 at 9:50 A.M., it was determined that the laboratory failed to test the CBC proficiency testing samples the same number of times that it routinely tests patient samples in the first testing event of year 2017 (March). The findings include: 1. On February 27, 2019 at 9:50 A.M., the P.R.PTP records showed that the laboratory tested in duplicate the 5 out of 5 CBC proficiency testing samples on 3/21/2017 (2017-131 to 2017-135) of the first testing event of year 2017 (March). 2. The laboratory general supervisor confirmed on February 27, 2019 at 9:50 A.M., that the laboratory did not test those CBC proficiency testing samples the same number of times that it routinely tests patient samples. She stated that the laboratory tested in duplicated the patients samples that showed panic value or value that showed discrepancy with the patients information or other parameters.

TESTING OF PROFICIENCY TESTING SAMPLES

CFR(s): 493.801(b)(4)

The laboratory must not send proficiency testing samples or portions of proficiency testing samples to another laboratory for any analysis for which it is certified to perform in its own laboratory. Any laboratory that CMS determines intentionally referred a proficiency testing sample to another laboratory for analysis may have its certification revoked for at least one year. If CMS determines that a proficiency testing sample was referred to another laboratory for analysis, but the requested testing was limited to reflex, distributive, or confirmatory testing that, if the sample were a patient specimen, would have been in full conformance with written, legally accurate and adequate standard operating procedures for the laboratory's testing of patient specimens, and if the proficiency testing referral is not a repeat proficiency testing referral, CMS will consider the referral to be improper and subject to alternative sanctions in accordance with 493.1804(c), but not intentional. Any laboratory that receives a proficiency testing sample from another laboratory for testing must notify CMS of the receipt of that sample regardless of whether the referral was made for reflex or confirmatory testing, or any other reason.

This STANDARD is not met as evidenced by:

Based on Puerto Rico Proficiency Testing Program (P.R.PTP) records review (years 2016, 2017 and 2018), laboratory general supervisor interview on February 27, 2019 at 9:30 A.M., and laboratory director phone interview on February 28, 2019 at 10:15 am., it was determined that the Laboratorio Clinico Central I (CLIA 40 D 0673051) processed the proficiency testing samples for CBC of the July 2018 and November 2018 P.R.PT events at Laboratorio Clinico Central II (CLIA 40 D 0952483) and reported those PT results as it's own. The findings include: 1. On February 27, 2019 at 9:30 A.M., the laboratory general supervisor stated that the laboratory did not perform the CBC tests since September 2017 due to the Hurricane Maria (the laboratory utilized the Coulter Act Diff 2 system for CBC tests and this system is out of service since the Hurricane Maria). However, the general supervisor stated that the laboratory processed proficiency testing samples for CBC tests during the year 2018. 2. The P.R. PTP records (Events of July 2018 and November 2018) showed that the Laboratorio Central I (CLIA 40 D 0673051) processed the CBC's proficiency testing samples of July 2018 and November 2018 events at Laboratory Central II (CLIA 40 D 0952483) and reported those PT results as its own. 3. The P.R.PT P records for the Events of July 2018 showed the following documents: a. Laboratory sheet standard 493.1236 for PT sample handling and processing: The laboratory director signed as evidence that she processed and reported the CBC proficiency samples by the Coulter Act Diff 2. However, those samples were processed by the Cell Dyn 1700 system at the Laboratorio Clinico Central II. Dated July 9, 2018. b. Proficiency Test form report of the Laboratorio Clinico Central I (CLIA 40 D 0673051); results reported by Internet and copy of the attestation) submitted on July 26, 2018. c. 6 out of 6 Prints out (poorly legible) of the five proficiency CBC testing sample results that were analyzed by the cell Dyn 1700 (CD1700 specimen data report). The first print out included the name of "Brenda". d. P.R. PT evaluation results sheet for Laboratorio Clinico Central I (CLIA 40 D 0673051): This records showed that the laboratory informed "120 Coulter" as the CBC tests method for the RBC, HCT HGB, WBC and platelet count. The laboratory obtained the following unsatisfactory results: RBC 60 %, HCT 20 % and Platelet count 40 %. e. The Standard #6 493.1236 sheet for PT evaluation was documented but not dated nor signed and includes the following documentation: Investigation: " The tests of platelet, hematocrit and RBC exceeded the established

limits. The system of the Central I could not be fixed. They don't get the spare part. I called up the P.R. PT program and they told me that the CBC proficiency testing sample of the Laboratorio Central I can be run by the Laboratorio Central II due to the Laboratorio Central II is the Referral laboratory of the Laboratorio Central I". Action plan: "observe the next event. Evaluation plan and corrective action: If the problem is not corrected, the CBC were not processed and referred to Central II. Comments: "the proficiency samples were received hot. They don't get on time. Could be affect the results. It was inform to the Department. 4. The P.R.PTP records for the Events of November 2018 showed the following documents: a. Laboratory sheet standard 493.1236 for PT sample handling and processing: The laboratory director signed as evidence that she processed and reported the CBC proficiency samples. This sheet did not include the name of the system where the proficiency samples were processed. b. P.R. Proficiency Test form report of the Laboratorio Clinico Central I (CLIA 40 D 0673051); results reported by Internet and copy of the attestation submitted on November 27, 2018. c. 5 out of 5 Prints out for the five proficiency CBC testing sample results that were analyzed by the cell Dyn 1700(CD1700 specimen data report). The 5 out of 5 prints out included the number of the proficiency testing sample (911, 912, 913, 914 and 915) and all were identified with letters C I, samples were processed on November 8, 2018. d. P.R. PT evaluation results for Laboratorio Clinico Central I (CLIA 40 D 0673051): This records showed that the laboratory informed "120 Coulter" the CBC tests method for the RBC, HCT HGB, WBC and platelet count. The laboratory obtained satisfactory results and obtained an 80% result in platelet count. e. The Standard #6 493.1236 sheet for PT evaluation was documented, dated : November 2018 and signed by the general supervisor and includes the following documentation: Investigation: "platelet under the expected. Samples processed at Central II". Situation Evaluation: "patients not affected. The quality control meet the established limits. Plan of corrective action: observes the next event. 5. The general supervisor confirmed on February 27, 2019 at 9:30 A.M., that the Laboratorio Central I (CLIA 40 D 0673051) processed the CBC's proficiency testing samples of the second (July) and the third (November) events of year 2018 at Laboratorio Central II (CLIA 40 D 0952483) and reported those PT results as its own. She stated that the laboratory director decided to process the CBC proficiency testing samples (Event July 2018 and Event November 2018) in the Laboratorio Clinico Central II (CLIA 40 D 0952483) by the Cell Dyn 1700 because the laboratory director called up the P.R. PT program and they told her that the CBC proficiency testing sample of the Laboratorio Central I can be run by the Laboratorio Central II due to the Laboratorio Central II is the Referral laboratory of the Laboratorio Central I". 6. During phone interview with the laboratory director on February 28, 2019 at 10:15 am, she stated that some one in the P.R.PTP instructed her to run the PT samples at the other laboratory because it was like an internal procedures due the fact that she was the owner and the laboratory director of both laboratories. She could not identified how told her the information.

D5209

PERSONNEL COMPETENCY ASSESSMENT POLICIES
CFR(s): 493.1235

As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.

This STANDARD is not met as evidenced by:
Based on personnel files (years 2017, 2018 and 2019) review and general supervisor

interview on February 27, 2019 at 12:15 PM, it was determined that the laboratory failed to follow the written procedures to monitor annually the competency evaluations of the clinical consultant from January 1, 2017 to January 30, 2019. The findings include: 1. The laboratory written procedures establish to monitor annually the competency evaluations of the clinical consultant from January 1, 2017 to January 30, 2019. 2. The clinical consultant personnel file showed that the laboratory did not evaluate annually the competence of the clinical consultant. The last competency evaluation in record was performed on January 9, 2017. 3. The general supervisor confirmed on February 27, 2019 at 12:15 PM, that the last competency in record for the clinical consultant was performed on January 9, 2017.

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:

1. Based on Quality Assessment (QA) written procedures review , QA records(years 2017, 2018 and 2019) review and general supervisor interview on February 27, 2019 at 10:50 AM, it was determined that the laboratory failed to follow the written procedures to assess the general laboratory systems for the complaints investigation requirement from February 2017 to February 2019. The findings include: a. On February 27, 2019 at 10:50 AM, the QA written procedures showed that the laboratory requires a monthly check to assess the complaints investigation requirement. b. The QA records showed that the laboratory did not document the log sheet designated to assess the complaints investigation requirement from February 2017 to February 2019. c. The general supervisor confirmed on February 27, 2019 at 10:50 AM, that the laboratory did not document the complaints investigation log sheet. She also stated that the laboratory did not receive any complaints from February 2017 to February 2019. 2. Based on Quality Assessment (QA) written procedures review , QA records(years 2017, 2018 and 2019) review and general supervisor interview on February 27, 2019 at 12:15 PM, 10:50 AM, it was determined that the laboratory failed to follow the written procedures to assess the general laboratory systems for the clinical consultant competency . Refer to D5209.

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 2017, 2018), annual tests volume record (year 2018), syphilis serology testing records (year 2018), serum pregnancy testing records (year 2018) review and general supervisor interview on February 27, 2019 at 12:30 PM, it was determined that the laboratory failed to indicate the name and address of the laboratory location in the following tests reports during the year 2018: urinalysis (440 patients specimens reports), serum pregnancy (10 patients specimens reports) and syphilis serology (22 patients specimens reports). The findings include: 1. The name and address of the laboratory location is Laboratorio Clinico Central I ; physical location Avenida Muoz Marin # 15, Humacao Puerto Rico , 00971. 2. On February 27, 2019 at 12:30 PM, the Laboratorio tests results records (urinalysis, serum pregnancy and syphilis serology) showed that all the tests results included name and address of the Laboratorio Clinico Central I I; physical location Avenida Font Martelo # 350, Humacao Puerto Rico , 00971. 3. The general supervisor confirmed on February 27, 2019 at 12:30 PM, that the tests reports include the information of the Laboratorio Clinico Central I I instead the required information of the Laboratorio Clinico Central I (name, laboratory address, CLIA number and State Law lic number). She stated that the Laboratorio Clinico Central I had problem to report with the laboratory information system (LIS) due to Hurricane Maria. She also stated that she processed the urinalysis, serum pregnancy and syphilis serology patients specimens in the Laboratorio Clinico Central I until 1:00 PM, then go to the the Laboratorio Clinico Central I I to report those tests. 4. The annual tests volume record, syphilis serology testing records and serum pregnancy testing records showed that the laboratory processed and reported the following patients specimens during the year 2018: 440 patients specimens for urinalysis, 10 patients specimens for serum pregnancy and 22 patients specimens for syphilis serology.

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 laboratory test reports records (years 2017, 2018), annual tests volume record (year 2018), syphilis serology testing records (year 2018), serum pregnancy testing records (year 2018), Puerto Rico Proficiency Testing Program (P.R.PTP) records (years 2016, 2017 and 2018), protocol for testing requirement of the proficiency testing samples , Quality Assessment (QA) written procedures review , QA records(years 2017, 2018 and 2019), personnel files (years 2017, 2018 and 2019) review and general supervisor interview on February 27, 2019 at 12:30 PM, it was determined that the laboratory director failed to fulfill her responsibilities and duties to ensure compliance with the following requirements: laboratory tests reports requirements, Proficiency Testing Program, quality assessment requirements and personnel competence. The findings include: 1. Refer to D 6079 (The laboratory director failed to fulfill her responsibilities and duties to ensure compliance with the laboratory tests reports requirements). 2. Refer to D 6088 (The laboratory director failed to enroll in an HHS approved Proficiency Testing Program for Complete blood count (CBC) with white blood cell (WBC) differential with three parameters since March 2017). 3. Refer to D 6089 (The laboratory director failed to ensure that the laboratory testing the CBC proficiency testing samples as required under subpart H (Participation in Proficiency Testing for Laboratories Performing Non-waived

	<p>Testing) from March 2017 to November 2018). 4. Refer to D 6094 (The laboratory director failed to ensure compliance with quality assessment (QA) requirements from February 2017 to February 2019). 5. Refer to D 6103 (The laboratory director failed to follow the written procedures to monitor the annual competency evaluations of the general supervisor.</p>
<p>D6079</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b)</p> <p>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 reappoints performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.</p> <p>This STANDARD is not met as evidenced by: Based on laboratory test reports records (years 2017, 2018), annual tests volume record (year 2018), syphilis serology testing records (year 2018), serum pregnancy testing records (year 2018) review and general supervisor interview on February 27, 2019 at 12:30 PM, it was determined that the laboratory director failed to fulfill her responsibilities and duties to ensure compliance with the laboratory test reports requirements. Refer D 5805.</p>
<p>D6088</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)</p> <p>The laboratory director must ensure that the laboratory is enrolled in an HHS-approved proficiency testing program for the testing performed.</p> <p>This STANDARD is not met as evidenced by: Based on Puerto Rico Proficiency Testing Program (P.R.PTP) records (years 2016, 2017 and 2018) review and laboratory general supervisor interview on February 27, 2019 at 9:50 A.M., it was determined that the laboratory director failed to enroll in an HHS approved Proficiency Testing Program for Complete blood count (CBC) with white blood cell (WBC) differential with three parameters since March 2017. Refer to D 2001.</p>
<p>D6089</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(i)</p> <p>The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on Puerto Rico Proficiency Testing Program (P.R.PTP) records (years 2016,</p>

2017 and 2018), protocol for testing requirement review of the proficiency testing samples and laboratory general supervisor interview on February 27, 2019 at 9:50 A. M., it was determined that the laboratory director failed to ensure that the laboratory testing the CBC proficiency testing samples as required under subpart H (Participation in Proficiency Testing for Laboratories Performing Non-waived Testing) from March 2017 to November 2018. The findings include: 1. On February 27, 2019 at 9:50 A.M., the laboratory did not have a protocol for the testing requirement of proficiency testing samples as required under subpart H. 2. Refer to D 2010 (The laboratory failed to test the CBC proficiency testing samples the same number of times that it routinely tests patient samples in the March 2017 event). 3 Refer to D 2013 (The Laboratorio Clinico Central I (CLIA 40 D 0673051) processed the proficiency testing samples for CBC of second (July) and third (November) year 2018 P.R.PT testing events at Laboratorio Clinico Central II (CLIA 40 D 0952483) and reported those PT results as its own). 4. The laboratory general supervisor confirmed on February 27, 2019 at 9:50 A.M, that the laboratory did not have a protocol for testing requirements of the proficiency testing samples. However, the Laboratory Proficiency protocol in records instructed the following: a. The proficiency samples will be rotated to every staff who performed each procedures. b. Use of leftover samples that are repeated by the other staff members after being reported. c. The personnel will participate in the Proficiency Program following the requirements of the Program. d. The evidence that personnel participate in the program and its performance which is measured by the program. It is important that the personnel in charge of an area perform the proficiency test. e. Will be documented on the competence evaluation form and reviewed with the staff.

D6094

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:
Based on Quality Assessment (QA) written procedures review , QA records(years 2017, 2018 and 2019) and general supervisor interview on February 27, 2019 at 10:50 AM, it was determined that the laboratory director failed to ensure compliance with quality assessment (QA) requirements from February 2017 to February 2019. The finding includes: 1. The laboratory director failed to assess the general laboratory systems for the complaints investigation requirement and for the clinical consultant competence. Refer to D 5291.

D6103

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(13)

The laboratory director must 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 files (years 2017, 2018 and 2019) review and general supervisor interview on February 27, 2019 at 12:15 PM, it was determined that the laboratory director did not assure the establishment written procedures for the supervisor competence assessment. The findings include: 1. On February 27, 2019 at 12:15 PM, the general supervisor's personnel records did not include a written procedures for her competence evaluation from 7/30/2017 to 1/30/2019. 2. The general supervisor stated on February 27, 2019 at 12:15 PM, that no written procedures were established for the superviosr competence.