| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 40D0697955 | 08/29/2019 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Laboratorio Clinico Chegar | Garcia De La Noceda B27 Villas De Rio Grande, Rio Grande, 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 |
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| **D2006** | TESTING OF PROFICIENCY TESTING SAMPLES<br>CFR(s): 493.801(b)<br><br>The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the proficiency samples testing, patients testing records and interview with the laboratory director on August 29, 2019 at 1:00 PM, it was found that the laboratory did not test the proficiency sample in the same manner as the patient samples. The findings include: a. The proficiency samples testing records for the first immunology testing event of year 2019 was reviewed on August 29, 2019 at 1:00 PM. b. The testing records showed that the HbsAg (Hepatitis B Surface Antigen) proficiency samples numbers 2019-211 and 2019-214 and the Human Immunodeficiency Virus (HIV) sample 2019-211 were repeated three times. c. The patient samples testinrecords showed that the patient's were tested only one time. c. The laboratory director stated that the patient's samples were not routinely repeated three times. Based on review of Proficiency Testing records in Bacteriology and interview with the general supervisor on August 29, 2019 at 12:45 pm, the laboratory failed to test the proficiency testing samples of event 1 2019 in the same manner as patient samples. the findings included: a. Vitek 2 worksheets showed PT sample # p2019633 was test three times on Aug. 6, 2019 at the following hours: 17:11, 18:25, and 17:12. b. Vitek 2 worksheets showed PT sample #p2019634-1 was tested two |

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| | times on August 8, 2019 @15:18 and August 9, 2019 @16:16 c. Vitek 2 worksheets showed PT sample #p2019634-1, Antimicrobial Sensitivity testing (AST), was tested two times on August 9, 2019 @ 1:13 and August 10, 2019 @1:17. d. Vitek 2 worksheets showed PT sample 2019635-1 was tested two times on August 8, 2019 @ 16:50 and August 9, 2019 @17.03 e. Vitek 2 Worksheets showed PT sample p2019635-1, Antimicrobial Sensitivity testing, was test two times on August 8, 2019 @21:34 and August 9, 2019 @22:16. f. The general supervisor stated she selected a colony from each plate to perform identification and AST. |
| **D5014** | GENERAL IMMUNOLOGY<br>CFR(s): 493.1208<br><br>If the laboratory provides services in the subspecialty of General immunology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, and 493.1281 through 493.1299.<br><br>This CONDITION is not met as evidenced by:<br>Based on Anti-HCV manufacturer's insert (Abbott) review on August 29, 2019 at 10: 30 AM and lack of performance verification procedures, it was determined that the laboratory failed to meet the requirements for Anti-HCV tests. Refer to: D5423- the laboratory did not establish the performance characteristics of the Anti-HCV test prior to use it with infants and children samples. |
| **D5217** | EVALUATION OF PROFICIENCY TESTING PERFORMANCE<br>CFR(s): 493.1236(c)(1)<br><br>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.<br><br>This STANDARD is not met as evidenced by:<br>Based on non-routine proficiency testing review and general supervisor interview on August 29, 2019 at 1:45 PM, it was determined that the laboratory failed to have and follow written procedures to verify the accuracy of the sperm motility and morphology since August 2017. The findings include: a. During the survey the written procedures to verify the accuracy of the sperm motility and morphology were requested. b. The general supervisor stated that there were no written procedures to verify the accuracy of the sperm motility and morphology. She also stated that in order to verify the accuracy of the test they used a proficiency testing samples (images) supplied from the WSLH proficiency testing program dated from years 2014 and 2015. The images were being used since year 2017. |
| **D5403** | PROCEDURE MANUAL<br>CFR(s): 493.1251(b)<br><br>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other |

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| | materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.<br><br>This STANDARD is not met as evidenced by:<br>Based on Ova and Parasite procedures manual, direct observation and interview with the testing personnel #5 on August 29, 2019 at 10:25 AM, it was determined that the laboratory failed to follow written procedure regarding the preparation and use of the Lugol's solution when 464 out of 464 ova and parasite patients specimens were examined and reported from January 1, 2019 to August 27, 2019. The findings include: a. The Ova and Parasite procedures manual showed that the Lugol's solution may be used up to ten days from the date of preparation. b. On August 29, 2019 at 10: 25 AM, the Lugol's solution was observed at the Ova and Parasite area, the label did not include the preparation date nor the expiration date. c. The testing personnel confirmed on August 29, 2019 at 10:25 AM, that the laboratory did not include the required information. She stated that the Lugol's solution was prepared monthly. d. The laboratory examined and reported 464 out of 464 ova and parasite patients specimens from January 1, 2019 to August 27, 2019. |
| **D5423** | ESTABLISHMENT AND VERIFICATION OF PERFORMANCE<br>CFR(s): 493.1253(b)(2)<br><br>Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance.<br><br>This STANDARD is not met as evidenced by:<br>Based on Abbott Architect Anti-HCV package insert, Architect i1000SR instrument verification of performance specifications, patient samples test reports from January 2088 to August 23, 2019 review and interview with the testing personnel #7 on August 29, 2019, it was found that the laboratory did not establish the performance specifications for infants and children populations. The findings include: a. The laboratory processed the Anti -HCV tests by the Architect i1000SR instrument . b. The Anti-HCV package insert intended use section showed the following: Assay performance characteristics have not been established for newborn, infants, children or populations of immunocompromised or immunosuppressed patients. The user is responsible for establishing their own assay performance characteristics in these |

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| | populations. c. During interview on August 29, 2019 at 10:30 AM, the testing personnel #7 stated that they performed Anti-HCV test for infants and children. d. The initial instrument verification procedures for the Architect i1000SR instrument was reviewed. The laboratory did not included infants nor children patients samples. e. Review patient's samples test reports from January 2018 to August 23, 2019 showed that a 28 out of 354 patient's samples were tested for Anti-HCV were from infants and children. |
| **D5439** | CALIBRATION AND CALIBRATION VERIFICATION<br>CFR(s): 493.1255(b)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on routine chemistry calibration verifications records reviewed ( 2018-2019) and laboratory routine chemistry supervisor interview on August 29, 2019 at 11:00 A. M., it was determined that the laboratory failed to perform at least every six months the calibration verification procedures for the routine chemistry tests. The findings include: 1.. The laboratory uses a Vitros 4600 system ( A and B) for routine chemistry tests. 2.. The laboratory establishes to perform routine chemistry calibration verifications each six month ( January and July ). 3. Review of calibration verification records from January 2018 to December 2018, showed that the laboratory did not perform the calibration verification procedures for sodium, potassium , chloride , urine protein and total iron binding capacity in January 2018. 4. The laboratory processed and reported the following patient tests from January 2018 to July 2018: BMP ( basic metabolic panel )- 1,136 CMP ( comprehensive metabolic panel ) - 4,439 TIBC- ( Total Iron Binding Capacity )-77 Urine protein-105 spot urine protein-517 5. Review of calibration verification records from January 2019 to August 29, 2019, showed that the laboratory did not perform the calibration verification procedures for urine protein and total iron binding capacity in January 2019 and July 2019. 6. The laboratory processed and reported the following patient tests from January 2019 to August 29, 2019: TIBC- ( Total Iron Binding Capacity )- 181 Urine protein- 192 spot |

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| | urine protein- 893 7. The laboratory director confirmed on August 29, 2019 at 1:30 P. M. , that the laboratory did not perform at least six months the calibration verification procedures for routine chemistry tests performed by the Vitros 4600 system. |
| **D5445** | CONTROL PROCEDURES<br>CFR(s): 493.1256(d)(1)(2)(g)<br><br>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--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of Individualized Quality Control Plan (IQCP) in Bacteriology and interview with the general supervisor at around 12:30 pm on August 29, 2019, the laboratory failed to develop complete IQCP Plans for the Vitek-2 identification system and antimicrobial Sensitivity test, and culture media. The findings included: a.. The IQCP for Vitek-2 identification system did not include Quality Control Plan (QCP and Quality Assessment (QA) section. b. The IQCP for exempt culture media did not include Quality Assessment (QA) section, and the QCP did not have the approval signature of the laboratory director. c. The IQCP for Vitek-2 Antimicrobial Sensitivity test (AST) did not include the approval signature of the laboratory director. |
| **D6093** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(5)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on routine chemistry calibration verification records (from year 2018-2019) review and interview with the laboratory director on August 29, 2019 at 1:30 P.M., it was determined that the laboratory director failed to ensure compliance with the requirements for routine chemistry tests. The finding includes: 1. The laboratory director did not ensure that the calibration verification procedures were performed each six months from year 2018-2019. Refer to D 5439. |
| **D6115** | TECHNICAL SUPERVISOR RESPONSIBILITIES<br>CFR(s): 493.1451(b)(2)<br><br>The technical supervisor is responsible for verification of the test procedures performed and establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system.<br><br>This STANDARD is not met as evidenced by: |

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| | Based on the lack of records , review of the Anti-HCV package insert and interview with the laboratory testing personnel #7 on August 29, 2019, it was found that the technical supervisor did not establish the performance specifications of the Anti-HCV test for infants and children prior to use it. The findings include: a. The Anti-HCV package insert instructed the laboratory to establish their own assay performance characteristics for infants and children populations. b. The technical supervisor did not establish the assay performance characteristics before use it with the mentioned population. Refer to D 5423. |
| **D6144** | GENERAL SUPERVISOR RESPONSIBILITIES<br>CFR(s): 493.1463<br><br>The general supervisor is responsible for day-to-day supervision or oversight of the laboratory operation and personnel performing testing and reporting test results.<br><br>This STANDARD is not met as evidenced by:<br>Based on Ova and Parasite procedures manual, direct observation and interview with the testing personnel # on August 29, 2019 at 10:25 AM, it was determined that the general supervisor failed to perform day-to-day supervision for the personnel that performing testing and reporting test results ova and parasite . The finding includes: a. The laboratory did not follow written procedure regarding the preparation and use of the Lugol's solution when 464 out of 464 ova and parasite patients specimens were examined and reported from January 1, 2019 to August 27, 2019. Refer to D 5403 |
| **D6177** | TESTING PERSONNEL RESPONSIBILITIES<br>CFR(s): 493.1495(b)(3)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on routine chemistry calibration verification records (from year 2018-2019) review and interview with the laboratory director on August 29, 2019 at 1:30 P.M., it was determined that the laboratory testing personnel failed to ensure compliance with the requirements for routine chemistry tests. The finding includes: 1. The laboratory testing personnel did not ensure that the calibration verification procedures were performed each six months from year 2018-2019. Refer to D 5439. |