| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 40D0871589 | 05/23/2023 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Laboratorio Clinico Moca | 90 Concepcion Vera, Moca, 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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| **D3000** | FACILITY ADMINISTRATION<br>CFR(s): 493.1100<br><br>Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe.<br><br>This CONDITION is not met as evidenced by:<br>Based on lack of Puerto Rico Proficiency Testing records ( PT) , Quality Assessment records QA) syphilis serology, endocrinology , general immunology quality control records and laboratory director interview at 1:30 p.m. on May 23, 2023, it was determined that the laboratory failed to keep quality control records, PT records and QA records. Refer D3031, D3037 and D3039. |
| **D3031** | RETENTION REQUIREMENTS<br>CFR(s): 493.1105(a)(3)<br><br>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.<br><br>This STANDARD is not met as evidenced by:<br>Based on lack of quality control records ( year 2023 ) and laboratory director |

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| | interview May 23, 2023 at 1:00 P.M., it was determined that the laboratory did not have quality control records. The findings include: 1. The laboratory performed syphilis serology tests , general immunology ( Rheumatoid factor and C-reactive protein ) , endocrinology (human chorionic gonadotropin) and Mycoplasma test. ( review on May 23, 2023 at 1:00 p.m ) 2. The laboratory did not keep records of the quality control records for : syphilis serology, general immunology not endocrinology since December 2022. ( review on May 23, 2023 at 1:05 p.m.) 3. The laboratory director confirmed on May 23, 2023 at 1:15 P.M. that she did not have evidence of the quality control records. Also, she was unable to give information about how many patients were processed and reported since December 2022. |
| **D3037** | RETENTION REQUIREMENTS<br>CFR(s): 493.1105(a)(4)<br><br>Proficiency testing records. Retain all proficiency testing records for at least 2 years.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of Puerto Rico Proficiency Testing records ( 2022--2023) and laboratory director interview on May 23, 2023 at 9:45 AM, it was determined that the laboratory failed to retain proficiency testing records for at least 2 years. The findings include: 1. Puerto Rico Proficiency Testing records were reviewed from February 2022 to October 2022. ( review on May 23, 2023 at 9:55 a.m. ) 2. The laboratory did not have available documentation ( results reported, test results scores, not attestation statements ) from November 2022 to May 2023. ( review on May 23, 2023 at 9:55 a. m. ) 3. The laboratory director confirmed on May 23, 2023 at 9:55 A.M. , that the laboratory did not have available the Proficiency Testing records at the laboratory since October 2022. |
| **D3039** | RETENTION REQUIREMENTS<br>CFR(s): 493.1105(a)(5)<br><br>Quality system assessment records. Retain all laboratory quality system assessment records for at least 2 years.<br><br>This STANDARD is not met as evidenced by:<br>Based on lack of Quality Assessment (QA) records and laboratory director interview on March 23, 2023 at 10:00 A.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 (pre-analytic, analytic and post-analytic systems) since December 2022. The findings include: 1. The laboratory did not evaluate the established Quality Assessment program since December 2022. 2. The laboratory director confirmed on March 23, 2023 at 10:15 A.M. , that the laboratory did not evaluate nor document the established Quality Assessment program in the laboratory since December 2022. |
| **D5012** | SYPHILIS SEROLOGY<br>CFR(s): 493.1207<br><br>If the laboratory provides services in the subspecialty of Syphilis serology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, and 493.1281 through 493.1299. |

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| | This CONDITION is not met as evidenced by:<br>Based on lack of syphilis serology testing record ( year 2022-2023 ) and laboratory director interview on May 23, 2023 at 1:20 P.M. , it was determined that the laboratory failed to ensure compliance with the analytic system requirements for syphilis serology tests. The finding includes: 1. The laboratory failed to follow the manufacturer's instruction when patient specimen were tested for RPR (Rapid plasma reagin) by ASI RPR method. ( refer to D5405 ) |
| **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 Mycoplasma pneumoniae and RA quality control records , patient records review ( year 2022-2023 ) and interview with the laboratory director on May 23, 2023 at 1:25 P.M., it was determined that the laboratory failed to meet the requirements in the subspecialty of General Immunology. The finding includes: 1. The laboratory failed to follow the manufacturer's instruction when patients specimens were tested and reported for of Mycoplasma pneumoniae and RA test. Refer to D5449. |
| **D5020** | ENDOCRINOLOGY<br>CFR(s): 493.1212<br><br>If the laboratory provides services in the subspecialty of Endocrinology, 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 serum Human Chrorionic Gonadotropin (hCG) test quality control records (years 2022-2023) and interview with the laboratory director on May 23, 2023 at 1:25 P.M. , it was , it was determined that the laboratory failed to ensure compliance with the analytic system requirements for serum hCG qualitative tests. The finding includes: 1. The human chrorionic gonadotropin (hCG) test quality control records (years 2022-2023) showed that the laboratory did not include each day of testing a negative and a positive control material when patients specimens were processed and reported for serum hCG qualitative test. Refer to D 5449. |
| **D5291** | GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT<br>CFR(s): 493.1239(a)<br><br>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. |

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| | This STANDARD is not met as evidenced by:<br>Based on lack of Quality Assessment (QA) activities records review ( year 2023 ) and laboratory director interview on May 23, 2023 at 10:15 A.M., it was determined that laboratory failed to evaluate and monitor the General Laboratory system requirements . The findings include: 1. On May 23, 2023 at 10:15 AM, the laboratory QA activities, since December 2022 , were requested. No QA record was available. 2. The laboratory did not have any evaluations related to: Patient confidentiality, specimen identification and integrity, compliant investigation and communications. 3. The laboratory director confirmed on May 23, 2023 at 10:15 A.M. that the QA evaluations 2023 were not available in the laboratory. |
| **D5391** | PREANALYTIC SYSTEMS QUALITY ASSESSMENT<br>CFR(s): 493.1249(a)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on quality assessment procedure manual, quality assessment ( QA ) records review (year 2022) and interview with the laboratory director interview on May 23, 2023 at 10:20 A.M., it was determined that the laboratory failed to follow the established Quality Assessment Program to monitor and evaluate the following requirements for preanalytic systems: patient test requests The findings include: 1. Review of the quality assessment program showed that evaluations to patient test request must be evaluated every six month. ( review on May 23, 2023 at 10:20 a.m. ) 2. Review of the quality assessment records showed that the last evaluation to patient test requests was performed in October 6, 2022 ( review on May 23, 2023 at 10:25 a. m. ) 3. The laboratory director confirmed on May 23, 2023 at 10:25 a.m. that evaluations to test requests were not performed. |
| **D5400** | ANALYTIC SYSTEMS<br>CFR(s): 493.1250<br><br>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.<br><br>This CONDITION is not met as evidenced by:<br>Based on lack of syphilis serology, general immunology and endocrinology quality control records from year 2023 and interview with the laboratory supervisor on May 23, 2023 at 1:30 p.m., it was determined that the laboratory failed to meet requirements for analytic systems. Refer to D 5012, D5014, and D5020. |
| **D5405** | PROCEDURE MANUAL<br>CFR(s): 493.1251(c)<br><br>Manufacturer's test system instructions or operator manuals may be used, when |

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| | applicable, to meet the requirements of paragraphs (b)(1) through (b)(12) of this section. Any of the items under paragraphs (b)(1) through (b)(12) of this section not provided by the manufacturer must be provided by the laboratory.<br><br>This STANDARD is not met as evidenced by:<br>Based on syphilis serology quality control records review ( years 2022-2023 ), patient's reports worksheets review and laboratory director interview on May 23, 2023 at 11:36 AM, it was determined that the laboratory failed to follow the manufacturer's instruction when patient specimen were tested for RPR (Rapid plasma reagin) by RPR card test ASI method. The findings include : 1. The syphilis serology quality control records were reviewed since January 2022. ( Review on May 23, 2023 at 11:40 AM. 2. The manufacturer's instruction establishes that three levels of control material ( non reactive, minimal to moderate and reactive) must be included each day of testing ( Review on May 23, 2023 at 11:42 AM.) 3. The laboratory did not have available the quality control logs, patient's report worksheets since December 2022. 4. The laboratory director stated on May 23, 2023 at 11:45 A.M., that the laboratory did not have available the syphilis serology quality control logs and patient's report worksheets from year 2023. 5. The laboratory performed and reported 83 syphilis serology patients samples from January 2023 to May 23, 2023. The laboratory did not have available during the survey how many patients were processed and reported since January 2023.. These data was sent to the SA office on May 30, 2023. |
| **D5413** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(b)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on laboratory preventive maintenance work sheets records review ( year 2022 ) and laboratory director interview on May 23, 2023 at 12:05 P.M., it was determined that the laboratory failed to monitor and document the laboratory's room temperature, relative humidity, voltage, refrigerator and freezer temperatures. The findings include: 1. The laboratory preventive maintenance work sheets from year 2022, establishes that the laboratory must monitor and document daily the room temperature, relative humidity, voltage, refrigerator and freezer temperatures. 2. Since December 31, 2022, the laboratory did not monitor the daily the room temperature, relative humidity, voltage not refrigerator and freezer temperatures. 3. The laboratory director stated on May 23, 2023 at 12:10 P.M., that the laboratory room temperature, relative humidity, voltage, refrigerator and freezer temperatures were not monitored not documented since December 31, 2022. |
| **D5429** | MAINTENANCE AND FUNCTION CHECKS<br>CFR(s): 493.1254(a)(1)<br><br>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory |

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| | must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.<br><br>This STANDARD is not met as evidenced by:<br>A. Based on Sysmex manufacturer's preventive maintenance written procedures and laboratory director at 11:00 a.m. on May 23, 2023, it was determined that the laboratory failed to follow written instructions for the preventive maintenance of Sysmex XS1000 i hematology systems. The findings include: 1. The Sysmex manufacturer's preventive maintenance procedures establishes that the laboratory must perform the daily ( shutdown) and monthly maintenance task ( running the monthly cleaning sequence ) . 2. The laboratory preventive maintenance records showed that the laboratory failed to perform nor document the daily and monthly preventive maintenance of the Sysmex XS1000 i hematology system since December 2022. 3. The laboratory director stated on May 23, 2023 at 11:10A.M., that the laboratory preventive maintenance records were not available at the laboratory. She alleged that the records were at her home. B. Based on laboratory preventive maintenance records review ( 2022-2023 ) and laboratory director interview on May 23, 2023 at 11:30 AM, it was determined that the laboratory failed to perform and document the preventive maintenance of each laboratory equipment and instrument (centrifuges , rotator and microscope) each day of use. The findings include: 1. Review of the laboratory preventive maintenance work sheets from year 2022, showed that the following preventive maintenance must be performed : Centrifuge ( external cleaning- daily, disinfection-weekly ), microscope ( daily cleaning ) and syphilis rotator ( every day-verify the rpm's ) . ( review on May 23, 2023 at 11: 35 A.M. ) 2. The laboratory did not perform not document the preventive maintenance of each laboratory equipment and instrument (centrifuges , rotator and microscope) each day of use, since December 2022. ( review on May 23, 2023 at 11: 35 A.M. ) 3. The laboratory director stated on May 23, 2023 at 11:35 A.M. , that the laboratory preventive maintenance records were not available in the laboratory. |
| **D5449** | CONTROL PROCEDURES<br>CFR(s): 493.1256(d)(3)(ii)(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-- 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.<br><br>This STANDARD is not met as evidenced by:<br>A. Based on endocrinology quality control records review ( years 2022-2023 ), patient's reports worksheets review and laboratory director interview on May 23, 2023 at 11:39 AM, it was determined that the laboratory failed to include a negative and positive control material each day of testing when reported and performed 24 out of 24 hCG test patient's samples in 2023. The findings include : 1. The laboratory performed hCG ( human chorionic gonadotropin) by one step method. ( Review on May 23, 2023 at 11:40 AM. 2. Endocrinology quality control logs and patient's reports worksheets were reviewed from January 2022 to December 2022. ( Review on May 23, 2023 at 11:40 AM.) 3. The laboratory did not have available the quality control logs, patient's report worksheets since December 2022. 4. The laboratory director stated on May 23, 2023 at 11:45 A.M., that the laboratory did not have |

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| | available the quality control logs and patient's report worksheets. 5. The laboratory performed and reported 24 hCG patients samples from January 2023 to May 23, 2023.. The laboratory did not have available quality controls records ( negative and positive control material ) since December 2022. B. Based on General Immunology (Mycoplasma pneumoniae test) quality control records review (years 2022-2033) and laboratory director interview on May 23, 2023 at 12:00 P.M., it was determined that the laboratory did not include an external positive and negative control material each day of Mycoplasma pneumoniae patient testing when reported and performed 123 out of 123 Mycoplasma patient's samples in 2023. The findings include: 1. The laboratory performed Mycoplasma Pneumoniae test by Immuno Card method. ( review on May 23, 2023 at 12:00 P.M. ) 2. General Immunology (Mycoplasma pneumoniae test) quality control records were review on January 2022 to December 2022. ( review on May 23, 2023 at 12:05 P.M. ) 3. Review of Mycoplasma pneumoniae quality control and patient results record showed that since December 2022 the laboratory did not include positive and negative control material each day of patient testing . ( review on May 23, 2023 at 12:05 P.M. ) 4.The laboratory reported and performed 123 Mycoplasma pneumoniae test from January 2023 to May 23, 2023. ( review on May 23, 2023 at 12:10 P.M. ) 5. The laboratory director stated on May 23, 2023 at 12:10 P. M. , that the laboratory did not have available the Mycoplasma quality control records from year 2023. C. Based on General Immunology ( Rheumatoid factor - RA ) quality control records review (years 2022-2033) and laboratory director interview on May 23, 2023 at 12:00 P.M., it was determined that the laboratory did not include an external positive and negative control material each day of RA patient testing when reported and performed 38 out of 38 RA patient's samples in 2023. The findings include: 1. The laboratory performed RA test by ASI method. ( review on May 23, 2023 at 12:00 P.M. ) 2. RA test quality control records were review on January 2022 to December 2022. ( review on May 23, 2023 at 12:05 P.M. ) 3. Review of RA quality control and patient results record showed that since December 2022 the laboratory did not include positive and negative control material each day of patient testing . ( review on May 23, 2023 at 12:05 P.M. ) 4.The laboratory reported and performed 38 RA test from January 2023 to May 23, 2023. ( review on May 23, 2023 at 12:10 P.M. ) 5. The laboratory director stated on May 23, 2023 at 12:10 P.M. , that the laboratory did not have available the RA quality control records from year 2023. |
| **D5471** | CONTROL PROCEDURES<br>CFR(s): 493.1256(e)(1)(g)<br><br>(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.<br><br>This STANDARD is not met as evidenced by:<br>Based on syphilis serology ( RPR test ) and general immunology ( RA ) quality control records ( year 2022-2023 ) . patient test records review from January 2022 to May 2023 and laboratory director interview at 11:52 a.m. , it was determined that the laboratory did not evaluate the new lots of reagent test for positive and negative reactivity prior to placed it in routine. The findings include: 1. Syphilis serology ( RPR test ) and general immunology ( RA ) tests quality control records were reviewed |

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| | from January 2022 to May 23, 2023.. 2. The laboratory received the following reagent kit and no evaluation of their reactivity were performed: Test Lot Expiration Date First day of use RPR 2BB7R6 11/30/23 12/2/22 RA 2J29D3 4/30/24 12/8/22 3. The laboratory processed and reported: RPR- 9 patient samples on December 2022 RA -7 patient samples on December 2022 4. The laboratory director confirmed on May 23, 2023 at 11:45 a.m. that the laboratory did not evaluate the new lots of RPR and RA for positive and negative reactivity prior to placed it in routine use. |
| **D5791** | ANALYTIC SYSTEMS QUALITY ASSESSMENT<br>CFR(s): 493.1289(a)(c)<br><br>(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.<br><br>This STANDARD is not met as evidenced by:<br>Based on quality assessment (QA) records review ( year 2022-2023 ) and laboratory director supervisor interview on May 23, 2023 at 10:30 A.M., it was determined that the laboratory failed to follow the established Quality Assessment Program to monitor and evaluate the requirement for analytic systems. The findings include: a. Review of the laboratory quality assessment records showed that the laboratory establishes a monthly assessment for each analytic process to keep track the laboratory performance. ( review on May 23, 2023 at 10:30 a.m. ) b. Since December 2022, the quality assessment (QA) records showed that the laboratory did not perform the monthly evaluation of the analytic system. ( review on May 23, 2023 at 10:30 a.m. ) c. The laboratory director confirmed on May 23, 2023 at 10:35 a.m., that the laboratory failed to perform the monthly evaluation of the analytic system. |
| **D6000** | MODERATE COMPLEXITY LABORATORY DIRECTOR<br>CFR(s): 493.1403<br><br>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.<br><br>This CONDITION is not met as evidenced by:<br>Based on lack of syphilis serology, general immunology, endocrinology quality control records, manufacturer's instructions review and laboratory director interview on May 23,2023 at 1:30 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<br>CFR(s): 493.1407(e)(5)<br><br>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 |

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| | 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.<br><br>This STANDARD is not met as evidenced by:<br>Based on quality control records review and laboratory director interview on May 23, 2023 at 1:30 P.M., it was determined that laboratory director failed to ensure compliance with the requirements for analytic systems. Refer to D5405, D5413, D5429, D5449 and D5471. |
| **D6021** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(5)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on Quality Assessment records review ( 2022-2023 ) and laboratory director interview on May 23, 2023 AT 1:30 P.M., it was determined that the laboratory director failed to ensure compliance with quality assessment requirements. Refer to D 5291 and D 5391. |