

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  40D0873472	<b>(X3) Date Survey Completed</b>  02/16/2023
<b>Name of Provider or Supplier</b>  Cdt Policlinica Familiar Factor Inc	<b>Street Address, City, State</b>  Carr Num 2 Km 65 Hm 6 Bo Factor I, Arecibo, PR	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2067</b>	<p><b>SYPHILIS SEROLOGY</b> CFR(s): 493.835(b)</p> <p>Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events.</p> <p>This STANDARD is not met as evidenced by: Based on Puerto Rico Proficiency Testing Program records reviewed ( 2021-2022) and laboratory director interview on February 16, 2023 at 9:10 A.M., it was determined that the laboratory failed to participate in the syphilis serology third testing event performed in December 2021. The findings include: 1. Proficiency testing records were reviewed from February 2021-December 2022. 2. The laboratory did not participate in the third testing event of syphilis serology performed in December 2021, a testing score of 0 % was obtained . ( review on 2/16/23 at 9:10 a.m. ) 3. The laboratory director confirmed on February 16, 2023 at 9:15 A.M., that the laboratory failed to participate in the third testing event of syphilis serology performed in December 2021.</p>
<b>D2077</b>	<p><b>GENERAL IMMUNOLOGY</b> CFR(s): 493.837(c)</p> <p>Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories</p>

failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events.

This STANDARD is not met as evidenced by:

Based on Puerto Rico Proficiency Testing Program records reviewed ( 2021-2022) and laboratory director interview on February 16, 2023 at 9:10 A.M., it was determined that the laboratory failed to participate in the general immunology third testing event performed in December 2021. The findings include: 1. Proficiency testing records were reviewed from February 2021-December 2022. 2. The laboratory did not participate in the third testing event of general immunology performed in December 2021, a testing score of 0 % in Mononucleosis test was obtained . ( review on 2/16/23 at 9:10 a.m. ) 3. The laboratory director confirmed on February 16, 2023 at 9:15 A.M., that the laboratory failed to participate in the third testing event of general immunology performed in December 2021.

**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 Immuno Card Mycoplasma manufacturer's instructions, General Immunology (Mycoplasma pneumoniae) testing record review from December 23, 2022 to February 16, 2023 and interview with the laboratory director on February 16, 2023 at 10:10 AM, it was determined that the laboratory failed to follow the manufacturer's instruction when 42 out of 42 patients specimens were tested and reported for of Mycoplasma pneumoniae from December 23, 2022 to February 16, 2023. The findings include: 1. The laboratory use the Immuno Card Mycoplasma Test to perform the Mycoplasma pneumoniae qualitative tests. 2. The manufacturer's instruction establishes to perform the test procedures at room temperature range from 22 to 25 C. ( review on February 16, 2023 at 10: 10 A.M. ) 3. On February 16, 2023 at 10:30 AM, review of the Mycoplasma pneumoniae testing records showed that the laboratory did not monitor nor document the room temperature when patient's specimens were tested for Mycoplasma by Immuno Card Meridian method from December 23, 2022 to February 16, 2023. 4. The laboratory director confirmed on February 16, 2023 at 10:40 AM, that the laboratory did not monitor nor document the room temperature when it processed the patients specimens for Mycoplasma pneumoniae test. 5. The laboratory processed and reported 42 out of 42 patient samples for Mycoplasma pneumoniae test from December 23, 2022 to February 16, 2023.

**D5435**

**MAINTENANCE AND FUNCTION CHECKS**

CFR(s): 493.1254(b)(2)

For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.

This STANDARD is not met as evidenced by:

Based on observation of preventive maintenance of the laboratory equipments and laboratory director interview on February 16, 2023 ay 10:30 A.M., it was determined that the laboratory failed to perform the preventive maintenance of the following equipments : centrifuge, microscope and rotator as established by the laboratory. The findings include: 1. The laboratory established to perform every year preventive maintenance for the following equipments : centrifuge, microscope and rotator;must be perform annually. 2. The laboratory did not perform the preventive maintenance of the centrifuge and microscope since May 2021. 3. The laboratory director stated on February 16, 2023 at 10:40 A.M., that these preventive maintenance must be perform annually and confirmed that the laboratory failed to ensure that these preventive maintenance were performed as establishes.

**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:

Based on General Immunology (Mycoplasma pneumoniae test) quality control records review (December 2022-February 2023) and laboratory director interview on February 16, 2023 at 10:15 A.M., it was determined that the laboratory did not include an external positive and negative control material when 42 out 42 Mycoplasma pneumoniae patient specimen were processed and reported since December 23, 2022. The findings include: 1. The laboratory begin to test Mycoplasma pneumoniae test on December 21, 2022. 2. General Immunology (Mycoplasma pneumoniae test) quality control records were review since December 23, 2022. ( reviewed on February 16, 2023 at 10:15 a.m. ) 3. Review of Mycoplasma pneumoniae quality control and patient results record showed that the laboratory did not include any control material each day of patient testing since December 23, 2022. ( reviewed on February 16, 2023 at 10:20 a.m. ) 4. The laboratory director confirmed on February 16, 2023 at 10:18 A. M., that the laboratory failed to include a negative and positive control material each day of testing when performed Mycoplasma pneumonia test. 5. The laboratory did not include any control material, when 42 out 42 patient specimen were processed and since December 23, 2022. ( reviewed on February 16, 2023 at 10:20 a.m. )

<p><b>D5525</b></p>	<p><b>PARASITOLOGY</b> CFR(s): 493.1264(b)(d)</p> <p>The laboratory must calibrate and use the calibrated ocular micrometer for determining the size of ova and parasites, if size is a critical parameter. (d) The laboratory must document all control procedures performed, as specified in this section.</p> <p>This STANDARD is not met as evidenced by: Based on Parasitology written procedures, observation of ocular micrometer calibration record ( label ) and interview with the laboratory director on February 16, 2023 at 10:30 AM, it was determined that the laboratory failed to follow written procedures to perform the annual calibration of the ocular micrometer used to determining the size of ova and parasites in patients stool specimens. The findings include: 1. The ocular micrometer calibration record showed that the laboratory did not calibrate the ocular micrometer since May 2021. ( reviewed on February 16, 2023 at 10:30 A.M. ) 2. The laboratory director confirmed on February 16, 2023 at 10:35 a. m., that the laboratory did not calibrate the ocular micrometer since May 2021. 3. The annual volume records showed that the laboratory examined 65 out of 65 parasitology patients during year 2022.</p>
<p><b>D6088</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> 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 Program testing records review ( 2021-2022 ) and laboratory director interview on February 16, 2023 at 9:10 a.m., it was determined that the laboratory director failed to ensure that the laboratory was enrolled in an HHS-approved proficiency testing program for the syphilis serology, general immunology and parasitology sub specialty . Refer to D2067 and D2077.</p>
<p><b>D6093</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1445(e)(5)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of General Immunology sub-specialty quality control records ( December 2022-February 2023 ) , review of equipment preventive maintenance records (year 2022) and interview with the laboratory director on February 16, 2023 at 11:00 A.M.; it was determined that the laboratory director failed to ensure the compliance of analytic systems. Refer to D5413, D5435, D5449 and D5525.</p>