

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D2030966	<b>(X3) Date Survey Completed</b>  05/24/2023
<b>Name of Provider or Supplier</b>  Miami Comprehensive Medicine Group Pa	<b>Street Address, City, State</b>  345 Palermo Avenue, Coral Gables, FL	
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>D0000</b>	A recertification survey conducted from 05/17/2023 to 05/24/2023 found the MIAMI COMPREHENSIVE MEDICINE GROUP PA clinical laboratory not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following condition was cited: -D5400 Analytic Systems.
<b>D2007</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to have all testing personnel (TP) rotate through the testing of Proficiency Testing (PT) for the Bacteriology and Virology sub-specialties in six out of seven events reviewed. Findings included: Review of FORM CMS-209 signed and dated by the Laboratory Director (LD) on 01/25/2023 revealed the laboratory had three TP listed (TP#A, TP# B and TP#C). -Review of personnel records revealed that TP#A had the initial evaluation on May 2021, TP#B had the initial evaluation on September 2021 and TP#C had initial evaluation in March 2022. -Review of American Proficiency Institute (API) PT records for 2021 (first, second and third event), 2022 (first, second and third event) and 2023 (first event), revealed: -TP#A performed six events: second and third event for 2021; first, second and third event for 2022 and first event for 2023. -Former employee TP#D performed first event of 2021. -There were no PT records for TP#B and TP#C. During an interview on 05/17/2023 at 11:30 AM, TP#A confirmed that the laboratory failed to rotate the PT between all TP for the period of reference.</p>
<b>D2009</b>	<b>TESTING OF PROFICIENCY TESTING SAMPLES</b>

CFR(s): 493.801(b)(1)

The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.

This STANDARD is not met as evidenced by:

Based on lack of attestation records and interview, the laboratory director (LD) and Testing Person (TP) failed to sign attestation for seven out of seven events reviewed for Bacteriology and Virology sub-specialties. Findings included: -Review of American Proficiency Institute (API) "ATTESTATION STATEMENT" revealed that "SIGNATURES REQUIRED- For all PT results, an attestation statement must be signed by Testing personnel and the laboratory director and retained for a minimum of 2 years. Either the attestation worksheet or this online statement may be used. Electronic signatures must have evidence that only authorized person can utilize the signature." - Review of PT records for 2021 (first, second and third event), 2022 (first, second and third event) and 2023 (first event), revealed that the LD and TP failed to sign the attestation for all the events of reference. During an interview on 05/17/2023 at 12:25 PM, TP#A confirmed that the laboratory failed to sign the attestation for the events of reference.

**D5400**

**ANALYTIC SYSTEMS**

CFR(s): 493.1250

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.

This CONDITION is not met as evidenced by:

Based on record review and staff interview, the laboratory did not meet the condition for analytic systems. Findings included: -Failure to run positive and negative controls with patients every testing date. Refer to 5449.

**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 record review and interview, the laboratory failed to run positive and negative external quality control for 386 out of 417 testing dates using the Biofire Respiratory Panel 2 RP 2.1. from 12/24/2020 to 05/17/2023. Findings included: - Review of the test menu revealed that the laboratory performed the following test:

Biofire Respiratory Panel 2 RP 2.1 that detects and identifies nucleic acid for the following respiratory pathogens: Adenovirus, Coronavirus 229E, Coronavirus HKU1, Coronavirus NL63, Coronavirus OC43, Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2), Human Metapneumovirus, Human Rhinovirus /Enterovirus, Influenza A H1-2009, Influenza A H3, Influenza B, Parainfluenza Virus 1, Parainfluenza Virus 2, Parainfluenza Virus 3, Parainfluenza Virus 4, Respiratory Syncytial Virus, Bordetella parapertussis (IS 1001), Bordetella pertussis (ptxP), Chlamydia pneumoniae, Mycoplasma pneumoniae. -Review of the Food and Drug Administration (FDA) "EVALUATION OF AUTOMATIC CLASS III DESIGNATION FOR BIOFIRE RESPIRATORY PANEL 2.1. DECISION SUMMARY" revealed that on page 16 it stated: "External controls should be used in accordance with laboratory protocols and the appropriate accrediting organization requirements as applicable." -Review of Patient log and External Quality Controls revealed that the laboratory performed 1091 tests from 12/24/2020 to 05/17/2023 and that the laboratory failed to use a positive and negative external control in 386 testing dates resulting on 958 tests performed with no external controls on the day of the testing. During an interview on 05/17/2023 at 11:45 AM the office manager confirmed that no positive and negative controls were run before patient testing on the days that 958 tests were performed.