Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2030966	11/12/2020
Name of Provider or Supplier	**Street Address, City, State**	
Miami Comprehensive Medicine Group Pa	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.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	An initial certification survey was conducted on 11-12-2020 at Miami Comprehensives Medicine Group PA clinical laboratory. The laboratory was not in compliance with 42 CFR Part 493, Requirements for Laboratories.
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 record review and interview, the laboratory failed to have job responsibility duties for the laboratory directory (LD) , Clinical Consultant (CC) , Technical consultant (TC) and Testing personnel (TP). Initial competency Assessment for 2 (#A and B) out of 2 CC were not completed in 2020 for COVID-19 testing . Findings Included: Review of CMS-209 Personnel Form displayed CC# A and CC#B as CC. Review of Competency Assessments revealed no documentation of initial competency assessments for CC#A and CC#B in 2020. Review of Personnel Duties Policy revealed no documentation of job responsibility duties for LD, CC, TC and TP. During an interview on 11-12-2020 at 3:30pm, the office manager confirmed initial competency assessments for 2(#A and B) out of 2 CC were not completed and no job responsibility descriptions for LD, CC, TC and TP.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) 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.

	This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to perform proficiency testing(PT) twice annually for COVID-19 PCR with BioFire instrument in 2020. Findings Included: Review of Proficiency Testing Folder revealed no PT documentation of enrollment and performance for COVID-19 PCR with BioFire instrument from July to November 12,2020. Review of Bio Fire Respiratory Panel Reports displayed COVID-19 patient testing reports from July to November 12,2020. During an interview on 11-12-2020 at 3:30pm, the office manager confirmed the laboratory failed to perform PT twice annually for COVID-19 PCR with Bio Fire instrument in 2020.
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: Based on record review and interview, the laboratory failed to monitor and create a policy for quality assurance (QA) from July 2020 to present. Findings Included: Review of Standard Operations manual revealed no policy for QA regarding COVID-19 PCR testing with BioFire. There was no documentation of QA monitoring from July 2020 to present. During an interview on 11/12/2020 at 3:00pm, the office manager confirmed the laboratory failed to monitor and create a policy for QA from July 2020 to present.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) 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 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. This STANDARD is not met as evidenced by:

	Based on record review and staff interview, the laboratory failed to create a specimen procedure for labeling and rejecting COVID-19 specimen in procedure manual . Findings Included : Review of procedure manual revealed no written instructions for labeling and rejecting COVID-19 specimen. During an interview on 11-12-2020 at 3: 30pm, the office manager confirmed the laboratory failed to have a specimen procedure for labeling and rejecting COVID-19 specimen.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to have the COVID-19 procedure manual signed and reviewed by the laboratory director (LD) in 2020 . Finding Included : Review of the COVID-19 Procedure Manual revealed no cover page with LD review and signature for 2020. During an interview on 11/12/2020 at 3: 30pm, the office manager confirmed the laboratory failed to have the COVID-19 procedure manual signed and reviewed by the LD in 2020 .
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) 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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory director (LD) failed to review and sign the validation for the BioFire PCR instrument used in COVID-19 testing from July 2020 to present. Finding Included : Review of the COVID-19 BioFire Validation revealed LD did not sign and review the equipment for COVID-19 PCR Testing . Review COVID-19 Results revealed BioFire performing COVID-19 testing from July 2020 to present. During an interview on 11/12/2020 at 3:30pm, the office manager confirmed the LD failed to review and sign the validation for the BioFire PCR instrument used in COVID-19 testing from July 2020 to present.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by:

	Based on record review and staff interview , the Technical Consultant (TC) failed to sign the COVID-19 competency assessments for 5(TP#A,TP#B,TP#Cand TP#D)out 5testing personnel(TP) in 2020. Findings Included : Review of CMS-209 Personnel Form displayed TP#A,TP#B,TP#Cand TP#D as TP. Review of COVID-19 Competency Assessments revealed a TP#A had signed for 5 out of 5 COVID-19 competency assessments for TP in 2020. There was no documentation of TC signing 5out of 5 COVID-19 competency assessments. During an interview on 11-12-2020 at 3:30pm, the office manager confirmed failed to sign the COVID-19 competency assessments for 5 out 5 testing personnel in 2020.