Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2229491	07/26/2023
Name of Provider or Supplier	**Street Address, City, State**	
Medflorida Medical Centers, Llc	1950 W Hillsboro Blvd Suite 103, Deerfield Beach, 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 conducted at MEDFLORIDA MEDICAL CENTERS LLC on 07/26/2023 found the clinical laboratory not in compliance with 42 CFR Part 493, Requirements for Laboratories.
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 Laboratory Consultant interview, the Laboratory Director (LD) failed to approve, sign and date the performance specification verification for the DXH 560 Hematology Analyzer, AU 480 Chemistry Analyzer and Access 2 Immunoassay analyzer before patient testing started on 07/01/2023. Findings included: -Review of performance specification verification records for the following analyzers revealed: a) Beckman Coulter DXH 560 Hematology Analyzer Checklist was signed by the Laboratory Consultant (LC) on 04/02/2023. b) Beckman Coulter AU 480 Chemistry Analyzer Simple Precision and Alternate Method Comparison Summary studies were signed by the LC on 04/30/2023. c) Beckman Coulter Access 2 Immunoassay Analyzer Linearity Simple, and Simple Precision studies were signed by the LC on 04/18/2023. During an Interview on 07/26/2023 at 02:30 PM, the LC confirmed that the LD failed to sign the performance verification studies for the analyzers listed above before the laboratory started patient testing.

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 review of personnel records and interview with Laboratory Consultant (LC) revealed that the initial and six-month competencies for one out of one Testing Personnel (TP) were not signed by the Technical Consultant in 2023. Findings included: -Review of FORM-209 (01/2021) signed and dated by the Laboratory Director (LD) on 07/20/2023, revealed that the LD, Clinical Consultant (CC) and Technical Consultant (TC) was the same person and that the laboratory had one TP (TP#A). -Review of personnel records revealed that the initial (02/14/2023) and six months (07/05/2023) competency evaluations for TP#A were not signed by the TC. During an interview on 07/26/2023 at 01:30 PM, with LC, he confirmed that the TC failed to sign the competencies of reference.