Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0295576	01/16/2023
Name of Provider or Supplier	**Street Address, City, State**	
Intercoastal Medical Group Inc	943 S Beneva Rd Ste 102, Sarasota, 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 announced CLIA recertification survey was conducted at Intercoastal Medical Group Inc on 01/12/23 - 01/16/23. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with the Laboratory Manager, the laboratory failed to have a procedure to verify the laboratory was correctly spinning coagulation citrate tubes at the correct speed and time to produce platelet poor plasma specimens for protime (PT) and Activated Partial Thromboplastin Time (APTT) testing for two out of two years reviewed (2020 - 2022). The laboratory had performed 3353 patients PT tests and 731 patients APTT tests from August 11, 2020 to January 12, 2023. Findings included: On 01/12/23 at approximately 9:00 am, observation revealed the laboratory was using a designated centrifuge that did not adjust for time and centrifuge speed when spinning coagulation specimens. The back of the centrifuge stated "3301 RPM [Revolutions Per Minute]" Interview with the Laboratory Manager at time of observation revealed the centrifuge produced a specimen that was acceptable for protime testing. Review of the Manufacturer's Instructions (MI) for the Sysmex CA - 600 series coagulation analyzer revealed "2. Centrifuge the blood tube directly after blood collection for 15 minutes at 1500 x g [force] to 2500 x g [force]. Please refer to CLSI [Clinical and Laboratory Standards Institute] guideline H21 - A5 [Collection, Transport, and Processing of Blood

	Specimens for Testing Plasma - Based Coagulation Assays and Molecular Hemostasis Assays] for further details." Review of the CLSI guidelines H21 - A5 revealed "To obtain a plasma sample, centrifuge the capped tube at a speed and time required to consistently produce platelet - poor plasma." Review of the laboratory's policies and procedures revealed the laboratory did not have a procedure for verifying the laboratory was correctly spinning coagulation citrate tubes at the correct speed and time to produce platelet poor plasma specimens for PT and APTT testing for two out of two years. On 01/12/2023 at 9:45 AM, the Laboratory Manager confirmed that there was no policy or procedure for producing a platelet poor plasma specimen for PT and APTT testing.