Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0966750	03/18/2020
Name of Provider or Supplier	**Street Address, City, State**	
Internal Medicine Of Southwest Florida	6311 S Pointe Blvd, Fort Myers, 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 certification validation survey was conducted on 3/18/20 at Internal Medicine of Southwest Florida, a clinical laboratory in Fort Myers, Florida. Internal Medicine of Southwest Florida is not in compliance with 42 CFR (Code of Federal Regulations), Part 493, requirements for clinical laboratories.
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on record review and interview with laboratory personnel, the laboratory had unsuccessful performance for a chemistry analyte over the past two years. The finding included: Review of proficiency testing records on 3/18/2020 revealed that the following unsuccessful events occurred: 1. The laboratory received 0% for blood urea

	nitrogen (BUN) on the first testing event of 2018 and 60% on the second testing event of 2018. During an interview with the testing person at 12:00 p.m. on 3/18/2020, she confirmed that they had received the unsuccessful scores.
D2096	ROUTINE CHEMISTRY CFR(s): 493.841(f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on record review and interview with laboratory personnel, the laboratory had unsuccessful performance for a chemistry analyte over the past two years. Finding include: Review of proficiency testing reccords on 3/18/2020 revealed that the following unsuccessful events occurred. The laboratory received 0% for blood urea nitrogen (BUN) on the first testing event of 2018 and 60% for the second testing event of 2018. During an interview with the testing person at 12:00 p.m. on 3/18/2020, she confirmed that they had received the unsuccessful scores.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on record review and interview with laboratory personnel, the laboratory did not calibrate the cell counter with the frequency indicated in the procedure manual. The findings included: Review of the procedure manual and calibration records on 3/18/2020 revealed that although the manual specified that the cell counter would be calibrated every six months, the cell counter was calibrated 7/2018, 7/2019, and 12/2019. During an interview with the testing person at 12:00 p.m. on 3/18/2020, she said that she must have missed the calibration at the end of 2018.