

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2038425	(X3) Date Survey Completed 02/25/2020
Name of Provider or Supplier Internal Medicine Associates	Street Address, City, State 1601 Clint Moore Rd Ste 200-02, Boca Raton, 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	A recertification survey conducted on 2-25-2020, found that Internal Medicine Associates clinical laboratory was not in compliance with 42 CFR Part 493, Requirements for Laboratories.
D5291	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to follow their Quality Assessment policy of documenting and reporting corrective actions for Hematology quality controls that reach out of the Standard deviation(SD) range with error flags on the Sysmex KX-21 machine for 2018 and 2019. Findings Include: A review of Quality Assessment Checklist record states that all quality control (QC) outliers and corrective actions will be documented. A review of Peer Group Comparison of Hematology Controls record revealed the Sysmex KX-12 had displayed machine flags and ranges over 2 SD from 2018 to 2019. A review of Quality Assessment Monthly Checklist record revealed that machine flags with Hematology quality controls from 2018 to 2019 were not documented. During an interview on 2-25-2020 at 11:30 am, the laboratory manager confirmed that Hematology quality controls SD ranges that were out with errors on Sysmex KX-21 were not documented.</p>