

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2100509	(X3) Date Survey Completed 03/25/2021
Name of Provider or Supplier Associates In Medicine & Surgery Llc	Street Address, City, State 9411 Fountain Medical Ct #E101, Bonita Springs, 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 recertification survey was conducted on 3/25/21 at Associates in Medicine & Surgery LLC, a clinical laboratory in Bonita Springs, Florida. Associates in Medicine & Surgery LLC is not in compliance with : Code of Federal Regulations (CFR) 42, Part 493, Laboratory Requirements. The following is a description of the noncompliance.
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with the laboratory consultant, the laboratory failed to verify the accuracy of Cytology testing at least twice a year for 1 year (2020) out of 2 years reviewed (2019-2020). Findings included: Review of Cytology peer reviews revealed that it was completed 7/19 and 1/20. In the laboratory's logbook there was a "Reconciliation of Quality Assurance Slide Review - Cytology" form that stated the explanation "No cytology cases 7-1 to 12/31" for not performing the 2nd verification of accuracy for 2020 Interview on 3/25/21 at 10:30 a.m., the laboratory consultant confirmed that the 2nd 2020 Reconciliation of Quality Assurance Slide Review - Cytology had not been performed because there was no patient testing. He did not know that the verification of accuracy must be performed twice annually even if patient testing was not performed.</p>