

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D0067532	(X3) Date Survey Completed 12/06/2019
Name of Provider or Supplier James Haines Md & William Belcastro Md	Street Address, City, State 299 Carew Street, Ste 322, Springfield, MA	
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 CLIA recertification survey was conducted for the James Haines, MD & William Belcastro, MD laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493. .
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, the laboratory failed to verify at least twice annually procedures it performs that are not included in subpart I of this part as evidenced by the following: a) A review of calendar years 2018 and 2019 (six testing events) proficiency testing records revealed that the laboratory had received an unacceptable score of zero (0)% for C-reactive protein for the first testing event of 2018 and a score of fifty (50)% for C-reactive protein for the second testing event of 2018. b) Based on the two unacceptable scores the laboratory had not demonstrated twice annual accuracy for the C-reactive protein analyte. c) The technical consultant interviewed on 12/6/19 at 9:20 AM was asked whether any other procedures were performed to verify the accuracy of C-reactive protein test results. She confirmed that no other procedures had been put into place to verify the accuracy of C-reactive protein test results twice annually.</p>