Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D0399412	12/03/2018
Name of Provider or Supplier	**Street Address, City, State**	
Aalfa Family Practice, Pa	4465 White Bear Parkway Suite 1, White Bear Lake, MN	

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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on document review and interview with laboratory personnel, the laboratory submitted eight proficiency testing (PT) samples to a reference laboratory on November 13, 2018. Refer to D2013.
D2013	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(4) The laboratory must not send proficiency testing samples or portions of proficiency testing samples to another laboratory for any analysis for which it is certified to perform in its own laboratory. Any laboratory that CMS determines intentionally referred a proficiency testing sample to another laboratory for analysis may have its certification revoked for at least one year. If CMS determines that a proficiency testing sample was referred to another laboratory for analysis, but the requested testing was limited to reflex, distributive, or confirmatory testing that, if the sample were a patient specimen, would have been in full conformance with written, legally accurate and adequate standard operating procedures for the laboratory's testing of

	patient specimens, and if the proficiency testing referral is not a repeat proficiency testing referral, CMS will consider the referral to be improper and subject to alternative sanctions in accordance with 493.1804(c), but not intentional. Any laboratory that receives a proficiency testing sample from another laboratory for testing must notify CMS of the receipt of that sample regardless of whether the referral was made for reflex or confirmatory testing, or any other reason. This STANDARD is not met as evidenced by: Based on document review, AALFA personnel interview, and complainant filing, AALFA Family Practice, PA laboratory improperly submitted PT samples to another laboratory. Findings are as follows: 1. On November 19, 2018, the director of a reference laboratory notified the Illinois State CLIA Program that the AALFA Family Practice, PA laboratory had sent an unopened bag containing eight PT samples to the reference laboratory. The samples arrived at the reference laboratory on November 14, 2018. 2. In an interview on December 3, 2018 at 12:30 p.m., AALFA Family Practice, PA personnel confirmed they sent PT samples from the third API Hematology PT event to the reference laboratory on November 13, 2018.