Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	22D0715393	03/21/2019
Name of Provider or Supplier	**Street Address, City, State**	
Framingham Pediatrics Pc	125 Newbury St, Ste 300, Framingham, 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 Framingham Pediatrics, PC laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493. Due to a repeat deficient practice cited herein, the following Condition level deficiency was deemed to be not met: 42 CFR 493.1403 - Condition: Laboratory Director. .
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on proficiency testing record review and confirmed through an interview on 3 /21/19 at 9:35 AM with one testing person, the laboratory failed to ensure that nineteen (19) out of twenty (20) testing personnel tested proficiency testing samples as evidenced by the following: 1. A review of proficiency testing record attestation statements for calendar years 2017 and 2018 (six testing events) revealed that only one of the personnel performing moderate complexity testing was also performing proficiency testing samples (documenetd signature on the attestation form). 2. Testing person number 8 interviewed confirmed that she was the only person routinely performing proficiency testing samples.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the

	manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for a newly introduced test system as evidenced by the following: Sysmex XP-300 hematology analyzer Within run precision: a) A review of the laboraory's validation study on 3/21/19 for the hematology analyzer revealed that no within run precision studies were available for review. b) The technical consultant interviewed on 3/21/19 at 11:42 AM confirmed that the technician who installed the analyzer and had performed some of the installation validation had told her that the analyzer was all set. .
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on the fact that a repeat deficient practice which had been previously cited, the laboratory director failed to provide overall management and direction in accordance with 493.1407 of this subpart as evidenced by the following: a) The laboratory director failed to ensure that laboratory personnel were performing the test methods as required for accurate and reliable results. (Refer to D6014)
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory director failed to ensure that laboratory personnel were performing the test methods as required for accurate and reliable results as evidenced by the following: 1. A review of seventeen (17) patient electronic medical records was performed for laboratory testing performed between 4/17/18 and 3/21/19. 2. During the review it was noted that one (1) of the seventeen (17) patients had rapid strep testing performed on a rectal/labia swab (patient medical record number 40288908) on 7/31/18. 3. The manufacturer's package insert for the rapid strep test system indicated that the test system was, "...intended for the detection of Group A Streptococcal antigen directly from throat swabs specimens". 4. The

	laboratory director interviewed on 3/21/19 at 11:20 AM confirmed that facility personnel had been advised that the practice of performing rapid strep testing on anything other than throat specimens was not allowed. She further stated that she was unaware that anyone in the practice was performing this type of testing. 5. This deficient practice of performing rapid strep testing on anything other that throat swab specimens was cited at a CLIA recertification survey performed on 3/26/15.