Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	07D0684911	10/18/2023
Name of Provider or Supplier	**Street Address, City, State**	
Francis X Walsh Md Pc	31 River Rd, Ste 200, Cos Cob, CT	

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
D5409	PROCEDURE MANUAL CFR(s): 493.1251(e) The laboratory must maintain a copy of each procedure with the dates of initial use and discontinuance as described in 493.1105(a)(2). This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to ensure the approved procedure for the Horiba ABX Pentra 60C+ contained the established normal ranges for Complete Blood Counts (CBC) in the specialty of hematology. Findings include: 1. Record review on 10/18/2023 of the 'ABX Pentra 60 C+ Laboratory Procedure Manual' revealed the lack of the following procedures: a. Reference ranges for male and female patients. b. Reportable ranges that correspond with the reportable ranges established and approved by the laboratory director (LD) during validation of the instrument. The laboratory was using the following reportable ranges for the following analytes: Male Female WBC: 4.5-10.5 4.0-10.0 RBC: 4.5-6.50 3.8-5.8 HGB: 13.0-17.0 11.5-16.0 PLT: 150-500 150-500 2. Record review on 10/18/23 of the Horiba ABX Pentra 60C+ validation records revealed the following reportable ranges were obtained and approved by the LD on 10/27/21. WBC: 0.4-138.32 RBC: 0.23-8.2 HGB: 0.66-24.55 PLT: 11.03-3093 3. Staff interview with the office manager on 10/18/23 at 11:30 AM confirmed the above findings. 4. The laboratory performs 3,551 CBC tests annually.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5)

	Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to ensure the final test reports included units of measurement for Complete Blood Counts (CBC) in the specialty of hematology. Findings include: 1. Record review on 10/18/2023 of the final test reports for patent #1 and 2 from the electronic medical record (Athena Health) revealed the lack of units of measurement for each CBC analytes. 2. Staff interview with the office manager on 10/18/23 at 11:40 AM confirmed the above finding. 3. The laboratory performs 3,551 CBC tests annually.
D5821	TEST REPORT CFR(s): 493.1291(k) When errors in the reported patient test results are detected, the laboratory must do the following: (k)(1) Promptly notify the authorized person ordering the test and, if applicable, the individual using the test results of reporting errors. (k)(2) Issue corrected reports promptly to the authorized person ordering the test and, if applicable, the individual using the test results. (k)(3) Maintain duplicates of the original report, as well as the corrected report. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to ensure the final CBC test reports from electronic medical record contained the correct reference ranges listed on the Horiba ABX Pentra 60 C+ instrument printouts in the specialty of hematology. Findings include: 1. Record review on 10/18/23 of the final EMR report for patient 1 (P-1) and patient 2 (P-2) revealed the following ranges were reported: Neutrophils# (NEU): 1.4-7.0 Lymphocytes# (LYM): 0.7-3.1 Monocytes# (MO): 0.4-0.9 2. Record review on 10/18/23 of the Horiba ABX Pentra 60C+ instrument printout for P-1 and P-2 revealed the following ranges were listed: Neutrophils# (NEU): 2.0-7.5 Lymphocytes# (LYM): 1-4 Monocytes# (MO): 0.2-1 3. Staff interview on 10/18 /2023 at 1:00 PM with the office manager confirmed the above findings. 4. The laboratory performs 3,551 CBC tests annually.