Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	07D0684911	02/24/2022
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
D2128	HEMATOLOGY CFR(s): 493.851(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to undertake and document appropriate remedial action for the unacceptable proficiency testing (PT) scores obtained in the specialty of hematology. Findings include: 1. Record review on 02/24/2022 of the laboratory's PT records from "AccuTest Performance Report Cycle 02-2020 for Instrument Model: ABX Micro 60 (CBC)" revealed the following: a. The analyte white blood cells (WBC) differential received an overall unacceptable score of 93.33% b. The analyte hematocrit % received an unacceptable score of 80.00%. c. Investigation and/or corrective action for the above unacceptable PT scores were not documented. 2. Record review on 02/24/2022 of the laboratory's PT records from "AccuTest Performance Report Cycle 03-2020 for Instrument Model: ABX Micro 60 (CBC) revealed the following: a. The analyte WBC Differential received an overall unacceptable score of 86.67% b. Documentation on the AccuTest Hematology-CMS Scoring Report stated, "Review WBC Diff. Called Horiba for Service" with no further investigation and/or corrective action to prevent recurrence. 3. Staff interview on 02/24/2022 at 12:37 PM with Testing Personnel confirmed there was no process in place for corrective action when unacceptable PT scores are obtained. 4. The laboratory performs 21,036 tests per year in the specialty of hematology

D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to ensure a complete procedure manual in the specialty of hematology. Findings include: 1) Record review on 02/24/2022 of the laboratory's "ABX Pentra 60 C+ PROCEDURE POLICY" revealed the following: a. Under the subheading 'Reportable Range:' the policy stated "it is recommended that the user confirm the Reportable range and/or Reference interval at time of installation. Please refer to CLIA for specific requirements when performing method evaluation studies." b. Reportable ranges for complete blood count (CBC) using the Horiba ABX Pentra 60 C+ instrument were not established as stipulated in line item (a) above. c. Under the subheading 'Normal and Panic Ranges' the policy stated "The DIFFERNTIAL normal ranges are factory set but may be adjusted for any of the analytes after calculating population means and SD ranges on your patient population." d. Normal and panic ranges for CBC were not established by the laboratory for the patient population tested as stipulated in line item (c) above: e. The laboratory procedure manual did not have a written protocol for reporting critical values. 2) Staff interview on 02/24/2022 at 1:10 PM with Testing Personnel confirmed the above findings. 3) The laboratory performs 21,036 tests per year in the specialty of hematology.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

	This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to provide evidence of monitoring and documenting humidity requirements. Findings include: 1. Record review on 02/24/2022 of the Horiba Medical ABX Pentra 60 C+ Hematology Analyzer User Manual revealed the following: a. "Instrument operating temperature: from +16C (+61F) to +34C (+93F). If the instrument is stored at a temperature lower than +10C (+50F), it should stand for one hour at a normal room temperature before use." b. "Humidity Conditions: Relative humidity of 80% maximum, without condensation." 2. Record review on 02/24/2022 of the laboratory temperature logs for the years 2020 and 2021 revealed room temperature or humidity were not documented in 2020 and 2021. 3. Staff interview on 02/24/2022 at 12:40 PM with testing personnel confirmed the above findings. 4. The laboratory performs 21,036 tests per year in the specialty of hematology.
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, surveyor observation, and staff interview the laboratory failed to ensure accurate and gender specific reference ranges were reported in the electronic medical records (EMR) system in concordance with the analyzer printouts. Findings include: 1) Record review on 02/24/2022 of the test report from the Horiba Medical ABX Pentra 60 C+ Hematology Analyzer for a female patient#1 (P1) revealed the reference ranges for the following analytes: a. WBC 4.0-10.0 10/mm b. RBC 3.80-5.80 10?/mm c. HGB 11.5-16.0 g/dl d. HCT 37.0-47.0 % e. MCV 80-100 m f. MCH 27.0-32.0 pg g. MCHC 32.0-36.0 g-dl h. RDW 11.0-16.0 % i. PLT 150-500 10/mm j. MPV 6.0-11.0 m 2) Record review on 02/24/2022 of the test report from the Horiba Medical ABX Pentra 60 C+ Hematology Analyzer for a male patient #2 (P2) revealed the reference ranges for the following analytes: a. WBC 4.0-10.0 10/mm b. RBC 4.50-6.50 10?/mm c. HGB 13.0-17.0 g/dl d. HCT 40.0-54.0 % e. MCV 80-100 m f. MCH 27.0-32.0 pg g. MCHC 32.0-36.0 g/dl h. RDW 11.0-16.0 % i. PLT 150-500 10/mm j. MPV 6.0-11.0 m 3) Surveyor observation on 02/24/2022 at 1:30 PM of the laboratory's EMR report for both P1 an P2 revealed the same reference ranges for both male and female patients were listed as follows: a. WBC 4.5-10.5 b. RBC 4.0-6.0 c. HGB 11.0-18.0 d. HCT 35.0-55.0 e. PLT 150-450 f. LYM 20.5-51.1 g. MON 1.7-9.3 h. GRA 42.2-75.2 No gender specific reference ranges were listed in the EMR report. 4) Staff interview with testing personnel on 02/24/2022 at 1:30 PM confirmed the ranges were discordant between the instrument print out and the EMR and was unaware of how to change the range in the EMR. 5) The laboratory performs 21,036 tests per year in the specialty of hematology.