

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  07D0684911	<b>(X3) Date Survey Completed</b>  08/28/2019
<b>Name of Provider or Supplier</b>  Francis X Walsh Md Pc	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2000</b>	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on record review and staff interview the laboratory failed to enroll in proficiency testing (PT) for the specialty of hematology. Findings include: 1. Record review of the Centers for Medicare Medicaid Services (CMS) CASPER Report 0155D on 8/28/19 revealed no scores for the following analytes for Event 1 2019: a. #0760 Hematology b. #0765 Cell I.D. or WBC Diff c. #0775 RBC d. #0785 HCT (Non-waived) e. #0795 HGB (Non-waived) f. #0805 WBC g. #0815 Platelets Scores of 100% for the above analytes for Event 2 2019 were documented utilizing the Accutest Inc. proficiency testing program. 2. Record review of the laboratory's test menu on 8/28/19 revealed the laboratory performs Complete Blood Counts (CBC) utilizing the Horiba ABX Micros 60 analyzer. 3. Staff interview with the testing personnel #1 on 8/28/19 at 1:14 PM confirmed the above findings. TP1 stated the accountant did not pay the PT program fee and therefore the laboratory was not enrolled until after Event 1 deadline had passed. 4. The laboratory performs 5,643 CBCs annually.</p>
<b>D5403</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p>

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 provide a complete procedure manual in the specialty of hematology. Findings include: 1. Record review of laboratory's procedure manual on 8/28/19 for the complete blood count (CBC) test revealed the lack of the following procedures: a. Specimen requirements and stability. b. Specimen acceptance and rejection criteria. c. Step by step performance of the CBC procedure. d. Calibration procedures. e. Instrument maintenance procedures. f. Quality control acceptability criteria. g. Corrective action for calibration or control result failures. h. Limitations in the test methodology, including interfering substances. i. Procedure when the system becomes inoperable. 2. Staff interview with the testing personnel #1 on 8/28/19 at 10:40 AM confirmed the procedure manual in the specialty of hematology is incomplete and needs to be updated. 3. The laboratory performs 5,643 CBC tests annually.

**D5415**

**TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT**  
CFR(s): 493.1252(c)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:

Based on surveyor observation, record review and staff interview, the laboratory failed to label quality control material with the appropriate expiration dates in the specialty of hematology. Findings include: 1. Surveyor observation of the Complete Blood Count (CBC) controls on 8/28/19 at 11:40 AM revealed the laboratory uses the Horiba Minotrol 16 Tri-Level controls (low, normal and high) and the current vials in use were opened on 8/18/19. No expiration date was noted on the vials. 2. Record review of the Horiba Medical Tri-level control manufacturer instructions on 8/28/19 revealed "unopened tubes are stable until the expiration date listed on the label.

Opened tubes are stable for 16 days". 3. Staff interview with testing personnel #1 and #2 on 8/28/19 at 11:40 AM stated controls were stable for 20 days and staff does not write the new expiration date on the tubes once they are opened. 4. The laboratory performs 5,643 CBC tests annually.

**D5429**

**MAINTENANCE AND FUNCTION CHECKS**  
CFR(s): 493.1254(a)(1)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:  
Based on record review and staff interview the laboratory failed to document routine maintenance and function checks for laboratory equipment in the specialty of hematology. Findings include: 1. Record review of the laboratory's January through August 2019 "At-A-Glance" paper calendars on 8/28/19 revealed the laboratory failed to document maintenance for the Horiba ABX Micros 60 analyzer, Serial Number 106CS906640, as required by the manufacturer. The calendar indicated check marks and "X" marks with no key indicating the meaning and no documentation of the testing personnel performing maintenance. 2. Review of the manufacturer's operator manual for the above equipment on 8/28/19 revealed that maintenance protocols need to be performed on a daily, as needed and PRN schedule in order to ensure accurate and reliable test results. 3. Staff interview with testing personnel #1 on 8/28/19 at 2:00 PM confirmed the calendar was not labeled and the laboratory failed to document maintenance for the above equipment as required by the manufacturer. 4. The laboratory performs 5,643 Complete Blood Count tests annually. This is a repeat deficiency.

**D5481**

**CONTROL PROCEDURES**  
CFR(s): 493.1256(f)(g)

(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:  
Based on surveyor observation, record review and staff interview, the laboratory failed to ensure remedial action was taken when quality control (QC) was out of range prior to testing and reporting patient samples in the specialty of hematology. Findings include: 1. Surveyor observation of the Complete Blood Count (CBC) controls on 8/28/19 at 11:40 AM revealed the laboratory uses the Horiba Minotrol 16 Tri-Level controls (low, normal and high). 2. Record review of the January 2019 monthly CBC quality control report on 8/28/19 revealed the following. a. QC lot number MX415 currently in use. b. Low Control was run on 1/22/19 at 8:50 AM with acceptable results. c. Normal Control on 1/22/19 was not run or documented. d. High Control on 1/22/19 was not run or documented. 3. Record review on 8/28/19 of the 'Quality Control Policies and Procedures' procedure revealed the following: a. "Run two controls for each test on each day test is run." b. "If both controls are within the acceptable range, patient samples may be tested and reported." 4. Record review on 8/28/19 of the laboratory test log for 1/22/19 revealed 13 patients were run and CBCs

reported with no documentation that two levels of controls were acceptable. 5. Staff interview with testing personnel #1 on 8/28/19 at 1:00 PM confirmed the above findings. 6. The laboratory performs 5,643 CBC tests annually.

**D5791**

**ANALYTIC SYSTEMS QUALITY ASSESSMENT**  
CFR(s): 493.1289(a)(c)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:  
Based on record review and staff interview, the laboratory failed to follow written quality assessment policies and procedures in the specialty of hematology. Findings include: 1. Record review of the laboratory's 'Quality Assurance Program' policy on 8/28/19 revealed: a. Personnel: "The laboratory personnel follow the manufacturer's instructions for test performance and troubleshooting". b. Patient test management /Record Keeping: "Copies of all test reports are readily accessible". c. "Quality Control (QC) samples are analyzed and documented each day of testing for non-waived tests, as specified in our procedure manual. Control results are within acceptable limits before patient samples are reported". 2. Record review of the 'January 2019 Quality Assurance Checklist' on 8/28/19 revealed the following: QC policies were marked "Y" (Yes) for the following: a. All reagents, controls, kits etc. that exceeded their expiration date were discarded. b. All instrument maintenance were performed and documented. c. Any necessary remedial action was performed and documented. d. All QC/calibrations were performed and were within acceptable limits before patient test results reported. e. QC results were examined for possible problems. f. The checklist was signed by the laboratory director on 1/31/19. 3. Record review of the January 2019 monthly 'CBC quality control report' on 8/28/19 revealed the following: a. QC lot number MX415 currently in use. b. Low Control was run on 1/22/19 at 8:50 AM with acceptable results. c. Normal Control on 1/22/19 was not run or documented. d. High Control on 1/22/19 was not run or documented. 4. Record review on 8/28/19 of the 'Quality Control Polices and Procedures' procedure revealed the following: a. "Run two controls for each test on each day test is run." b. "If both controls are within the acceptable range, patient samples may be tested and reported." 5. Record review on 8/28/19 of the laboratory test log for 1/22/19 revealed 13 patients were run and CBCs reported with no documentation that two levels of controls were acceptable. Results were manually recorded in the electronic medical record (EMR) and the instrument printouts were not documented in the EMR. 6. Record review of the laboratory's January through August 2019 "At-A-Glance" paper calendars on 8/28/19 revealed the laboratory failed to document maintenance for the Horiba ABX Micros 60 analyzer, Serial Number 106CS906640, as required by the manufacturer. The calendar indicated check marks and "X" marks with no key indicating the meaning and no documentation of the testing personnel performing maintenance. 7. Review of the manufacturer's operator manual for the above equipment on 8/28/19 revealed that maintenance protocols need to be performed on a daily, as needed and PRN schedule in order to ensure accurate and reliable test results. 8. Staff interview with the testing personnel #1 on 8/28/19 at 2:00 PM confirmed the above findings. 9. The laboratory performs 5,643 Complete Blood Count tests annually.

**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 record review and staff interview, the laboratory director failed to provide overall management and direction in accordance with 493.1407. The cumulative effect of this lack of oversight resulted in the laboratory director's inability to ensure the accuracy and reliability of patient test results in the subspecialty of hematology. Findings include: 1. The laboratory director failed to ensure the laboratory was enrolled in proficiency testing for regulated analytes in subpart I. Refer to D6015. 2. The laboratory director failed to ensure testing systems developed and used by the laboratory provide quality services for all aspects of test performance. Refer to D6020. 3. The laboratory director failed to ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. Refer to D6021. 4. The laboratory director failed to ensure that patient test results are reported only when the test system is functioning properly. Refer to D6025.

**D6015**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(4)

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)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed.

This STANDARD is not met as evidenced by:  
Refer to D2000.

**D6020**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(5)

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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:  
Refer to D5481.

**D6021**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(5)

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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:  
Refer to D5791.

**D6025**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(7)

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)(7) Ensure that patient test results are reported only when the system is functioning properly.

This STANDARD is not met as evidenced by:  
Refer to D5481.