Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D0242641	03/17/2020
Name of Provider or Supplier	**Street Address, City, State**	
Washington Regional Medical Center	958 Us Highway 64 East, Plymouth, NC	

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 review of 2019 and 2020 API (American Proficiency Institute) proficiency testing records 3/16/20 and 3/17/20 and interview with the GS (general supervisor) 3 /17/20, the laboratory failed to enroll in proficiency testing for all required tests in 2019 and 2020. Review of 2019 and 2020 API proficiency testing records revealed: 1. The laboratory's 2019 API order confirmation included the Immunology Package which contained Infectious Mononucleosis and RF (rheumatoid factor). During interview 3/17/20 at approximately 10:05 a.m., the GS stated that the first event arrived while the facility was closed, so the samples were shipped back to API. When the facility reopened in May 2019, the GS stated they had to contact API to request shipment of the remaining events. She stated the Immunology Package must have been overlooked and not requested. She verified they did not test any Infectious Mononucleosis and RF proficiency samples in 2019. 2. The laboratory failed to enroll in proficiency testing for Infectious Mononucleosis and RF in 2020.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)

	Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on review of 2018, 2019, and 2020 hematology calibration records, and interview with GS(general supervisor) 3/16/20, the laboratory failed to retain all calibration records for at least two years. Findings: Review of 2018, 2019, and 2020 Sysmex XS-1000i hematology records revealed the laboratory failed to retain copies of calibrator assay sheets used for calibrations for the primary hematology analyzer (Serial #68089) on 6/19/18, 12/10/18, 5/20/19, and 2/13/20 and for secondary hematology analyzer (Serial #68088) on 6/13/18, 12/3/18, 5/20/19, and 2/13/20. During interview at approximately 3:45 p.m., the GS stated the service representative told her the calibrator assay sheets did not need to be kept.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of 2019 API (American Proficiency Institute) proficiency testing records 3/16/20 and 3/17/20 and interview with the GS (general supervisor) 3/17/20, the laboratory failed to enroll in proficiency testing or establish a system to verify the accuracy of all tests not included in subpart I during 2019. Review of 2019 API proficiency testing records revealed the laboratory failed to participate in proficiency testing or establish a system to verify the accuracy of the following tests in 2019: 1. C-Reactive Protein 2. Ferritin 3. Folate 4. IBC (iron binding capacity) 5. PSA (prostate specific antigen) 6. PTH (parathyroid hormone) 7. Testosterone 8. Transferrin 9. Vitamin B12 10. Vitamin D 11. Urine drug screen (amphetamines /methamphetamines, barbiturates, benzodiazepines, cannabinoids, cocaine, opiates, phencyclidine) During interview at approximately 10:05 a.m., the GS stated that the samples for 2019 API 1st event arrived while the facility was closed and the samples were returned to API. When the facility reopened in May 2019, the GS stated they had to contact API to request shipment of the remaining events. She stated the modules that included the above analytes must have been overlooked and not requested. The GS confirmed that the laboratory did not perform any activity (split sample testing, etc.) to verify the accuracy of the tests that were not included in proficiency testing.
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 review of 2018, 2019 and 2020 laboratory temperature and humidity logs, and interview with General Supervisor (GS) 3//17/20, the laboratory failed to perform and/or document corrective action when humidity ranges were below acceptable limits for accurate and reliable test results. Findings: Review of 2018, 2019 and 2020 laboratory temperature and humidity logs "Daily Temperature and Humidity Side B" revealed the laboratory defined humidity range for "Side B" of the laboratory is 30-80%. Review of 2018, 2019 and 2020 "Daily Temperature and Humidity Side B" logs revealed the laboratory failed to perform and/or document correction action when the humidity was below the acceptable range during the following time periods in which patients were tested: a. In 2018, 3 of 30 days in November; and 18 of 31 days in December. b. In 2019, 22 of 31 days in January, 8 of 21 days in February, 8 of 31 days in November and 14 of 31 days in December. c. In 2020, 15 of 31 days in January, 13 of 29 days in February and 6 of 27 days in March. During interview 3/17 /20, at approximately 10:15 a.m., the GS stated Side B of the laboratory is where the hematology and coagulation analyzers are. She confirmed that the laboratory had not documented corrective action for the unacceptable humidity ranges. She also stated they have always had problems with humidity in that area of the laboratory and they normally just turn on the humidifier when ranges were below acceptable limits. She confirmed that the laboratory had not documented corrective action for the unacceptable humidity ranges and had not recorded new humidity readings if they had performed any corrective action.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on review of 2018, 2019, and 2020 Sysmex XS-1000i hematology QC(Quality Control) records, review of manufacturer's product insert, and interview with GS (general supervisor) 3/17/20, the laboratory failed to discard control materials that had exceeded the expiration date. Findings: Review of hematology QC records and Sysmex e-check(xs) hematology control product insert revealed control material was expired and used on the following: a. lot # 8184, expired 9/23/18, in use 9/24/18-10/25 /18- approximately 442 patients tested; b. lot #8240, expired 11/18/18, in use 11/19 /18- approximately 17 patients tested; c. lot #9099, expired 6/30/19, in use 7/1/19-7/2 /19- approximately 23 patients tested; d. lot #9267, expired 12/15/19, in use 12/16/19-12/17/19- approximately 25 patients tested. During interview at approximately 8:30 a. m., the GS confirmed expired controls were tested with a patient control daily between 9/24/18-10/25/18 due to inability to obtain control material because manufacturer was requiring payment in advance.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions;

	(b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, review of 2018, 2019, and 2020 Hematology calibration records, and interview with GS(general supervisor) 3/16/20, the laboratory failed to perform and document calibration of the Sysmex XS-1000i hematology analyzers at least once every six months. Findings: The manufacturer's instructions state, "Following installation calibration, the operator is requested to verify instrument calibration every 6 months or on an 'as needed' basis, and maintain good QC practices, to ensure the accuracy of the system." Review of the 2018, 2019, and 2020 Sysmex XS-1000i hematology calibration records revealed both primary and secondary hematology analyzers were calibrated on 5/20/19 and not again until 2 /13/20. During interview at approximately 3:45 p.m., the GS confirmed the calibrations were performed past the 6-month time-frame. She stated she was waiting for the Sysmex service representative to schedule the calibrations with the preventative maintenance visit.
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 review of laboratory procedure and review of 2019 domain dimer (D-dimer) quality control (QC) records 3/17/20, the laboratory failed to ensure QC results were acceptable prior to reporting patient test results. Findings: Review of laboratory procedure "Innovance D-Dimer" revealed "...Quality Control: ..INNOVANCE D-Dimer Control 1...INNOVANCE D-Dimer Control 2...(5)...f....Both levels of Quality Control must be within acceptable limits prior to resulting patient samples." Review of D-dimer QC records revealed on 9/15/19 the QC for Innovance D-Dimer Control 1, Lot # 562297, was not within acceptable limits prior to reporting patient test results. One patient was tested when QC was not acceptable.
D5545	HEMATOLOGY

	CFR(s): 493.1269(b)(d) (b) For all nonmanual coagulation test systems, the laboratory must include two levels of control material each 8 hours of operation and each time a reagent is changed. (d) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of laboratory procedures, review of 2018, 2019, and 2020 QC (Quality Control) records, review of patient results, and interview with GS(general supervisor) 3/17/20, the laboratory failed to perform and document quality control for the Sysmex CA600 coagulation analyzer. Findings: The laboratory procedure for PT (prothrombin time) and procedure for aPTT(activated partial thromboplastin time) state, " 1. Controls must be tested upon reagent changes, and every 8 hours plus or minus 30 minutes...If controls are not run within time specified, no patients may be tested or reported. Document 'no patients run' on the log sheet and run the controls before the next patient." Review of 2018, 2019, and 2020 Sysmex CA600 QC records for PT and aPTT revealed QC was not performed or documented for the 3-11 p.m. shift on 9/15/19, and one patient was tested. At approximately 11:15 a.m., the GS confirmed the QC for PT and aPTT was missed.