Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	30D0920300	10/07/2020
Name of Provider or Supplier	**Street Address, City, State**	
Saco River Medical Group Pc	7 Greenwood Ave, Conway, NH	

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	Survey report revised on 11/13/20. D6020 revised to reflect the correct referenced tag in findings, changed to D5781 (from D5481). D6022 removed; Deficient practices cited under D6022 also cited under D6020, D6021 and D6026.
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's procedure manual failed to include reportable ranges for hematology in 2019 and 2020. Findings include: 1) Review on 10/7/2020 of the laboratory's verification of performance specifications revealed the laboratory obtained a new instrument for complete blood count (CBC)

	testing and completed the verification in December 2019. The verification of performance specifications included verification of reportable ranges for CBC analytes. 2) Review on 10/7/2020 of the laboratory's complete blood count (CBC) procedure manual revealed no reportable ranges for CBC analytes were included in the procedure manual. 3) Interview with Staff A (laboratory supervisor) on 10/7/2020 at approximately 1:00 p.m. confirmed the above findings.
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 maintain service records performed by the manufacturer for unscheduled maintenance on the hematology analyzer in August 2020. Findings include: 1) Review on 10/7/2020 of "SRMG Coulter DxH 520 QC Daily / Maintenance Log" for July and August 2020 revealed on 8/28/2020 the complete blood count (CBC) analyzer was serviced by the manfuacturer due to control failures. 2) The laboratory could not provide the manufacturer's 8/28/2020 service records at the time of survey on 10/7/2020. 3) Interview with Staff A (laboratory supervisor) on 10/7/2020 at 11:30 a.m. confirmed the above findings.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed document corrective action (CA) taken when hematology control results failed acceptable criteria in August 2020. Findings include: 1) Review on 10/7/2020 of complete blood count (CBC) control records from 7/27/2020 through 9/5/2020 revealed the laboratory failed to document corrective action taken when the control materials from lot 35202 (expiration 10/5/2020) failed to meet acceptable criteria. Level 1: 8/9/2020 - Failed, 1 attempt, no corrective action documented. 8/13/2020 - Passed, 3 attempts, no documentation of corrective action. 8/17/2020 - Passed, 3 attempts, no documentation of corrective action. 8/18/2020 - Passed, 3 attempts, no documentation of corrective action. 8/20/2020 - Passed, 8 attempts, no documentation of corrective action. 8/21 /2020 - Passed, 4 attempts, no documentation of corrective action. 8/22/2020 - Passed, 3 attempts, no documentation of corrective action, time between attempts 2 and 3

	nearly 8 hours. Level 2: 8/15/2020 - Passed, 3 attempts, no documentation of corrective action. 8/24/2020 - Passed, 3 attempts, no documentation of corrective action. 8/25/2020 - Passed, 3 attempts, no documentation of corrective action. 8/26 /2020 - Passed, 4 attempts, no documentation of corrective action. 8/27/2020 - Failed, 3 attempts, 2nd event passed, level ran a third time unexplainably and failed - no corrective action documented. Level 3: 8/3/2020 - Failed, 1 attempt, no corrective action documented. 8/8/2020 - Passed, 3 attempts, no documentation of corrective action. 8/10/2020 - Failed, 1 attempt, no corrective action documented. 8/17/2020 - Failed, 1 attempt, no corrective action documented. 8/18/2020 - Passed, 4 attempts, no documentation of corrective action. 8/21/2020 - Passed, 5 attempts, no documentation of corrective action. 8/22/2020 - Passed, 4 attempts, no documentation of corrective action. 8/24/2020 - Passed, 4 attempts, no corrective action documented. 8/25/2020 - Passed, 10 attempts, no corrective action documented. 8/26/2020 - Failed, 6 attempts, no corrective action documented. 8/27/2020 - Passed, 3 attempts, no corrective action documented. 2) Interview with Staff A (laboratory supervisor) confirmed the CBC control log failed to include all corrective action steps taken when CBC controls failed to meet acceptable criteria.
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's procedures for monitoring hematology control testing failed to identify and correct problems with control testing when they occurred in August 2020. Findings include: 1) Review on 10/7/2020 of the laboratory's procedure for complete blood count (CBC) control testing revealed instruction that results for all (3 of 3) control materials must fall within their acceptable range. Further review revealed after two attempts to obtain acceptable results had been made, testing personnel was to troubleshoot and correct the cause of failed control testing which included review of expiration dates, amount of control material and calling the manufacturer for assistance and then repeat testing a third time. 2) Review on 10/7/2020 of CBC control records from 7/27/2020 through 9/5 /2020 revealed CBC control results had been reviewed by Staff A (laboratory supervisor), and the control materials from lot 35202 (expiration 10/5/2020) failed to meet acceptable criteria and/or personnel failed to follow control procedures for troubleshooting control failures, and document corrective action taken during troubleshooting: Level 1: 8/9/2020 - Failed, 1 attempt, no corrective action documented. 8/13/2020 - Passed, 3 attempts, no documentation of corrective action. 8 /17/2020 - Passed, 3 attempts, no documentation of corrective action. 8/18/2020 - Passed, 3 attempts, no documentation of corrective action. 8/20/2020 - Passed, 8 attempts, no documentation of corrective action. 8/21/2020 - Passed, 4 attempts, no documentation of corrective action. 8/22/2020 - Passed, 3 attempts, no documentation of corrective action, time between attempts 2 and 3 nearly 8 hours. Level 2: 8/15/2020 - Passed, 3 attempts, no documentation of corrective action. 8/24/2020 - Passed, 3 attempts, no documentation of corrective action. 8/25/2020 - Passed, 3 attempts, no documentation of corrective action. 8/26/2020 - Passed, 4 attempts, no documentation of corrective action. 8/27/2020 - Failed, 3 attempts, 2nd event passed, level ran a third

	time unexplainably and failed - no corrective action documented. Level 3: 8/3/2020 - Failed, 1 attempt, no corrective action documented. 8/8/2020 - Passed, 3 attempts, no documentation of corrective action. 8/10/2020 - Failed, 1 attempt, no corrective action documented. 8/17/2020 - Failed, 1 attempt, no corrective action documented. 8/18 /2020 - Passed, 4 attempts, no documentation of corrective action. 8/21/2020 - Passed, 5 attempts, no documentation of corrective action. 8/22/2020 - Passed, 4 attempts, no documentation of corrective action. 8/23/2020 - Failed, 3 attempts, corrective action documented - no acceptable control testing afterwards. 8/24/2020 - Passed, 4 attempts, no corrective action documented. 8/25/2020 - Passed, 10 attempts, no corrective action documented. 8/26/2020 - Failed, 6 attempts, no corrective action documented. 8 /27/2020 - Passed, 3 attempts, no corrective action documented. 3) Interview with the Staff A (laboratory supervisor) on 10/7/2020 at 11:30 a.m. revealed the laboratory uses the manufacturer's assayed ranges for acceptable criteria of the 3 levels of CBC control material and no follow up had been conducted with testing personnel when the control procedure had not been followed and when 1 of 3 control levels failed acceptable criteria.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory's hematology report failed to include pertinent reference intervals for adult females. This is a repeat deficiency from the recertification survey completed on 5/25/2018. Findings include: 1) Review on 10/7/2020 of the laboratory's complete blood count (CBC) procedure manual revealed the following reference ranges for female patients 13 years of age and older: white blood cell count (WBC) 4.2-10.2 x 10^3/uL; red blood cell count (RBC) 3.8-5.1 x 10^6/dL; hemoglobin (HGB) 11.8-15.8 g/dL, and hematocrit (HCT) 35.0 - 47.0 %. 2) Review on 10/7/2020 of complete blood count (CBC) reports from September 2020 revealed 2 of 2 female patient CBC reports included the following reference ranges: WBC 4.2-9.9 x 10^3/uL; RBC 4.08-5.75 x 10^6/dL; HGB 13.0-17.4 g/dL; and HCT 38.0-50.0 %. 3) Interview with Staff B (testing personnel) on 10/7/2020 at approximately 1:00 p.m. confirmed the above findings and revealed the ranges included on the reports were for adult male patients.
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 for hematology testing in 2020. Findings include: 1) The laboratory director failed to ensure the quality control program is maintained to assure quality of hematology test results. Refer to tag D6020. 2) The laboratory

	director failed to ensure quality assessment programs for hematology testing identified and corrected failures in control testing as they occurred. Refer to tag D6021. 3) The laboratory director failed to ensure quality assessment programs for hematology are maintained to identify failures in quality as they occur in 2020. Refer to tag D6022. 4) The laboratory director failed to ensure hematology test reports include the correct reference intervals for adult female patient results in 2020. Refer to tag D6026. 5) The laboratory director failed to specify in writing the responsibilities and duties of each person engaged in preanalytic, analytic and postanalytic phases of hematology testing in 2019 and 2020. Refer to tag D6032.
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: Based on record review and staff interview, the laboratory director failed to ensure the quality control program is maintained to assure quality of hematology test results. Refer to tag D5781.
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: Based on record review and staff interview, the laboratory director failed to ensure quality assessment programs for hematology testing identified and corrected failures in control testing as they occurred. Refer to tag D5791.
D6026	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(8) 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)(8) Ensure that reports of test results include pertinent information required for interpretation.

	This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory director failed to ensure hematology test reports include the correct reference intervals for adult female patient results in 2020. Refer to tag D5807.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) 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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory director failed to specify in writing the responsibilities and duties of each person engaged in preanalytic, analytic and postanlytic phases of hematology testing in 2019 and 2020. Findings include: 1) The Surveyor requested the description of responsibilities and duties for the laboratory supervisor on 10/7/2020. The laboratory was unable to provide this documentation at the time of survey. 2) Interview with Staff A (laboratory supervisor) on 10/7/2020 at approximately 1:00 p.m. revealed there were no written responsibilities and duties of each laboratory personnel, including the responsibilities for Staff A.