

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 30D0920300	(X3) Date Survey Completed 05/25/2018
Name of Provider or Supplier Saco River Medical Group Pc	Street Address, City, State 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
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <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.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory's procedure manual failed to include reference intervals and critical values for hematology tests. Findings include: 1) Review on 5/25/18 of three patient reports from May 2018 for complete blood count (CBC) testing revealed reference intervals were included on the final reports. The CBC report for the adult male patient (one of three CBC reports reviewed) included reference intervals that were different to those intervals included on the adult female patient (one of three CBC reports reviewed). The reference intervals for a male pediatric patient (6 years old) included the same reference</p>

intervals as the adult male. CBC analytes include white blood cell count (WBC), white blood cell differential count, red blood cell count (RBC), hemoglobin, hematocrit (HCT), and platelet count (PLT). 2) Review on 5/25/18 of the instrument printouts corresponding to the three final patient CBC reports reviewed revealed the reference intervals did not match those included on the final reports and it was noted on the instrument printout that the reference ranges on the CBC instrument printout were for adults only and not applicable to newborn/pediatric patients. Further review revealed the criteria for critical values of WBC, RBC, HCT, and PLT were included on the CBC instrument printouts. 3) Review on 5/25/18 of the laboratory's procedure manual for CBCs revealed no reference intervals (reference ranges) and alert (critical) values were included in the procedure manual. 4) Interview on 5/25/18 at 12:30 p.m. with the general supervisor confirmed the laboratory's procedure manual did not include the reference intervals and alert values for CBC analytes. 5) The laboratory performs an estimated 1,100 CBC tests annually.

D6063

LABORATORY TESTING PERSONNEL
CFR(s): 493.1421

The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.

This CONDITION is not met as evidenced by:
Based on record review and staff interview, the laboratory failed to ensure new testing personnel hired in 2017 and 2018 met qualification requirements for moderately complex hematology testing. Findings include: 1) Personnel records failed to include documentation that educational qualification requirements had been met for five of six new testing personnel performing patient complete blood count testing. Refer to tag D6065.

D6065

TESTING PERSONNEL QUALIFICATIONS
CFR(s): 493.1423(b)(1)(2)(3)(4)(i)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:
Based on record review and staff interview, new testing personnel hired in 2017 and 2018 failed to meet qualification requirements for moderately complex hematology testing. Findings include: 1) Review on 5/25/18 of personnel records revealed five of six testing personnel hired in 2017 and 2018 did not have documentation of meeting educational qualification requirements. Further review of these records revealed all

five had been trained in and had begun performing patient complete blood count testing. 2) Interview on 5/25/18 at 11:15 a.m. with the general supervisor confirmed the personnel records for five of the six new testing personnel hired in 2017 and 2018 did not include documentation that educational qualification requirements were met.