Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	30D0086768	01/10/2018
Name of Provider or Supplier	**Street Address, City, State**	
Cottage Hospital	90 Swiftwater Rd, Woodsville, 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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on record review and staff interview, laboratory personnel failed to attest to the routine integration of chemistry, microbiology, immunohematology, and hematology proficiency testing (PT) samples using the laboratory's routine methods for PT in 2017. Findings include: 1) Review on 1/9/18 of PT records from 2017 revealed laboratory personnel failed to attest to the routine integration of PT samples following American Proficiency Institute PT events: 6 out of 7 testing personnel failed to sign the attestation form for the "2017 Chemistry Miscellaneous 2nd Event;" 2 out of 6 testing personnel failed to sign the attestation form for "2017 Chemistry Core 1st Event;" 2 out of 6 testing personnel failed to sign the attestation form for " 2017 Chemistry Core 3rd Event;" 4 out of 6 testing personnel failed to sign the attestation form for "2017 Hematology/Coagulation 2nd Event;" 4 out of 6 testing personnel failed to sign the attestation form for "2017 Hematology/Coagulation 3rd Event;" 3 out of 6 testing personnel failed to sign the attestation form for "2017 Microbiology 3rd Event;" 2 out of 5 testing personnel and the laboratory director failed to sign the attestation form for "2017 Immunology/Immunohematology 1st Event;" 2 out of 5 testing personnel and the laboratory director failed to sign the attestation form for "2017 Immunology/Immunohematology 2nd Event;" and, 1 out of 5 testing personnel and the laboratory director failed to sign the attestation form for "2017 Immunology /Immunohematology 3rd Event." 2) Interview on 1/9/18 at 11:30 a.m. with the Technical Supervisor and Laboratory Director confirmed the above finding.
D5543	HEMATOLOGY

	CFR(s): 493.1269(a)(d) (a) For manual cell counts performed using a hemocytometer-- (a)(1) One control material must be tested each 8 hours of operation; and (a)(2) Patient specimens and control materials must be tested in duplicate. (d) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to document duplicate test counts for two levels of control materials used for manual cell counts. Findings include: 1) Review on 1/10/2018 of the Body Fluid Control Log from October 4, 2016 through December 31, 2017, revealed the laboratory documented one test count for each level of control material used for manual cell counts performed on the hemocytometer. 2) Review on 1/10/2018 of the laboratory procedure "Synovial Fluid Analysis" last revised 6/25/2008, revealed when the laboratory uses a hemocytometer to perform manual cell counts it will perform two counts, one on each side of the hemocytometer, and document both counts on the Body Fluid Control Log. 3) Interview on 1/10/2018 at 12:30 p.m. with the Technical Supervisor (TS) revealed testing personnel were performing cell counts for both control materials in duplicate. TS confirmed that two separate counts were not documented on the Body Fluid Control Log from October 4, 2016 through December 31, 2017. 4) Review 1/10/2018 of patient records from 10/4/2016 to 12/31/2017 revealed the laboratory performed and reported a total of 39 manual patient cell counts.
D5821	TEST REPORT CFR(s): 493.1291(k) When errors in the reported patient test results are detected, the laboratory must do the following: (k)(1) Promptly notify the authorized person ordering the test and, if applicable, the individual using the test results of reporting errors. (k)(2) Issue corrected reports promptly to the authorized person ordering the test and, if applicable, the individual using the test results. (k)(3) Maintain duplicates of the original report, as well as the corrected report. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to document notification of corrected chemistry and hematology results when errors in patient tests results were detected. Findings include: 1) Review on 1/10/2018 of corrected reports from June 2017 through November 2017 revealed prompt notification was not documented when corrections were made to 38 patient test results. 2) Review on 1/10 /2018 of the laboratory's procedure titled "Detection and Documentation of Clerical Errors, Analytical Errors and Unusual Results," effective 8/7/2017, revealed no instruction to notify and document notification of correction of patient test results. 3) Interview on 1/10/2018 at 11:00 a.m. with the Technical Supervisor confirmed the above findings.
D6072	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(3) Each individual performing moderate complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument

	and procedural calibrations and maintenance performed. This STANDARD is not met as evidenced by: Based on record review and staff interview, testing personnel performing moderately complex hematology testing failed to adhere to the laboratory's quality control policies for complete blood cell counts (CBC). Findings include: 1) Review on 1/10 /2018 of the laboratory's procedure titled "Complete Blood Count CBC (xs1000i)" effective 10/2012 revealed instruction to check expiration dates of control material, remix the control vials, and rerun CBC controls when results are not acceptable. If repeat CBC control testing is still out of acceptable range, open new CBC control material vials. 2) Review on 1/10/2018 of CBC control records from November 2017 to January 10, 2018 revealed on 12/16/2017 the platelet count was unacceptable for CBC control level three and was not repeated. 3) Review on 1/10/2018 of patient records revealed 16 patient CBC results had been reported on 12/16/2017. 4) Interview on 1/10/2018 at 10:30 a.m. with the Technical Supervisor confirmed the above findings.