Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	47D1003387	07/16/2018
Name of Provider or Supplier	**Street Address, City, State**	
Lake Champlain Gynecologic Oncology	1060 Hinesburg Rd, Ste 301, South Burlington, VT	

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
D2006	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b) The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to test one of five hematology proficiency samples in the same manner that it routinely tests patient samples for one of three events in 2017. This is a repeat deficiency. Findings include: 1) Review on 7/16/18 of complete blood count (CBC) proficiency testing (PT) records from 2016, 2017, and 2018 revealed in the second event (one of three events) of 2017, PT sample 9 (one of five samples) was tested twice by two different testing personnel prior to the due date for submitting results. 2) Interview on 7/16/18 at 12:00 p.m. with Staff A (testing personnel) confirmed the above finding. Staff A (testing personnel) revealed that patient CBC testing is routinely performed by one testing personnel, not two. 3) This is a repeat deficiency from the recertification survey conducted on 7/18 /2016.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples.

	The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to maintain documentation of hematology proficiency sample testing for two proficiency testing (PT) events in 2016 and 2017. Findings include: 1) Review on 7/16/18 of complete blood count (CBC) PT records from 2016 (one PT event), 2017 (three PT events) and 2018 (three PT events) revealed the laboratory failed to maintain documentation of CBC instrument print outs for five of five PT samples in the third event of 2016 and first event of 2017. 2) Interview on 7/16/18 at 12:00 p.m. with Staff A (testing personnel) confirmed the CBC instrument printouts for the third PT event in 2016 and first PT event in 2017 had not been saved.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to verify the accuracy of hematology testing not scored by the proficiency testing (PT) program for one event in 2017. due to not submitting all results prior to the due date in 2017. Findings include: 1) Review on 7/16/18 of complete blood count (CBC) PT records from 2016 (one event), 2017 (three events) and 2018 (three events) revealed the laboratory failed to submit results for red cell distribution width (RDW), granulocytes, lymphocytes, and monocytes for five of five PT samples from the second event in 2017 and obtained a score of "0" for each of these analytes. There was no documentation that the laboratory evaluated their results obtained for these analytes with expected results from the PT program. 2) Interview on 7/16/18 at 12:00 p.m. with Staff A (testing personnel) confirmed the laboratory did not evaluate their results for RDW, granulocytes, lymphocytes, and monocytes were within the acceptable ranges.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by:

	Based on record review and staff interview, the laboratory failed to evaluate unacceptable hematology proficiency testing (PT) results obtained one event in 2017. Findings include: 1) Review on 7/16/18 of complete blood count (CBC) PT records from 2016 (one event), 2017 (three events) and 2018 (three events) revealed the laboratory obtained unacceptable results for hematocrit, hemoglobin, red cell count, and white cell count for sample "HEM-6" (one of five samples) in the second PT event of 2017. Further review revealed the laboratory did not investigate and document, as part of the evaluation, the unacceptable results for PT sample "HEM-6." 2) Interview on 7/16/18 at 12:00 p.m. with Staff A (testing personnel) confirmed the laboratory did not investigate as part of their evaluation, why the laboratory obtained unacceptable results for PT sample "HEM-6."
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to perform hematology control testing on one day of patient testing in June and July 2018. Findings include: 1) Review on 7/16/18 of control records from June 2018 through July 12, 2018 revealed no complete blood count (CBC) control materials were tested on June 29, 2018. 2) Review on 7/16/18 of patient CBC test records revealed two patient CBCs were tested and reported on June 29, 2018. 3) Review on 7/16/18 of the laboratory's procedure manual for "ACT Diff-II Operations Instructions - Running the Control" revealed instruction on page 1 to perform control testing "every working day." 4) Interview on 7/16/18 at 11:15 a.m. with Staff A (testing personnel) confirmed two patient CBCs had been reported on June 29, 2018 when CBC control testing had not been performed. Staff A revealed that it was common practice to perform CBC control testing on the days that the office was open and CBC testing was anticipated.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed.

	This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to verify the manufacturer's stated values of assayed control materials used for hematology and chemistry testing in 2016, 2017 and 2018. Findings include: 1) Review on 7/16/18 of control records from June and July 2018 revealed the laboratory used assayed control materials for complete blood counts (CBC) and cancer antigen-125 (CA-125) testing. Further review of control records revealed the laboratory failed to run new lots of CBC and CA-125 control materials prior to putting the new lots into use. 2) Review on 7/16/18 of the laboratory's CBC and CA-125 procedure manuals revealed no instruction to verify the assayed ranges provided by the manufacturers prior to putting the control materials into use. 3) Interview on 7/16/18 at 1:15 p.m. with Staff A (testing personnel) and Staff B (testing personnel) confirmed the laboratory did not verify the manufacturer's ranges for control materials prior to putting them into use and revealed that the lab has never verified these ranges for new lot numbers of control materials prior to using the control materials.