Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	47D1003387	10/23/2020
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
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, testing personnel and the laboratory director failed to sign the attestation form for 8 of 13 routine chemistry and hematology proficiency testing (PT) events in 2018, 2019, and 2020. Findings include: 1) Review on 10/23/2020 of the laboratory's American Proficiency Institute (API) PT records for 7 complete blood count (CBC) events in 2018, 2019, and 2020 revealed testing personnel and the laboratory director failed to sign the attestation page for 5 of 7 events. Review of the laboratory's API PT records from 2018, 2019, and 2020 for cancer antigen 125 (CA 125) revealed testing personnel and the laboratory director failed to sign the attestation page for 3 of 6 PT events. 2) Interview with Staff A (testing personnel) on 10/23/2020 at approximately 12:00 p.m. confirmed the above finding.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.

	This CONDITION is not met as evidenced by: Based on record review and staff interview, the laboratory failed to meet analytic system requirements for chemistry and hematology testing in 2018, 2019, and 2020. Findings include: The laboratory failed to perform and document maintenance for the hematology analyzer in 2019 and 2020. Refer to tag D5429. The laboratory failed to perform hematology calibration procedures in 2019 and 2020. Refer to tag D5437. The laboratory failed to document control procedures for chemistry testing in September 2020. Refer to tag D5447. The laboratory failed to document control procedures for chemistry testing after calibration in September 2020. Refer to tag D5461. The laboratory failed to perform and document corrective action when chemistry control results failed to meet manufacturer's assayed ranges in 2020. Refer to tag D5781. The laboratory failed to establish and maintain procedures for monitoring the quality of analytic systems used for routine chemistry and hematology testing in 2018, 2019, and 2020. Refer to tag D5791.
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 lack of documentation and staff interview, the laboratory failed to perform and document maintenance for the hematology analyzer in 2019 and 2020. Findings include: 1) Maintenance records for the Beckman Coulter AcT-Diff2 (Beckman) analyzer from 2019 and 2020 were requested by the surveyor on 10/23/2020. The laboratory could not provide the requested maintenance records at the time of the survey. 2) Interview with Staff A (testing personnel) on 10/23/2020 at 2:45 p.m. revealed maintenance performed in 2020 included replacing the lamp and cleaning /washing cycles. These maintenance activities were not documented and Staff A could not recall specifically any other maintenance that had been performed in 2019 and 2020. Staff A confirmed maintenance on the Beckman analyzer is not documented. 3) The Beckman analyzer is used to perform approximately 151 complete blood count tests annually.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.

	This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to perform hematology calibration procedures in 2019 and 2020. Findings include: 1) Review on 10/23/2020 of Beckman Coulter AcT-Diff2 analyzer calibration reports for complete blood counts revealed the last calibration was performed in July 2018. There were no records of the laboratory performing calibrations in 2019 or 2020. 2) Interview with Staff A (testing personnel) on 10/23/2020 2:45 p.m. confirmed the laboratory had not calibrated the CBC analyzer since July 2018. Staff A further revealed the laboratory was not aware they need to perform it.
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 document control procedures for chemistry testing in September 2020. Findings include: 1) Review on 10/23/2020 of patient testing records from 8/23/2020 to 10/23/2020 for cancer antigen 125 (CA 125) revealed 15 patient CA 125 tests had been performed and reported on 9 /20/2020. 2) Review on 10/23/2020 of CA 125 control records from 8/23/2020 to 10 /23/2020 revealed no control records for 9/20/2020. 3) Interview with Staff A (testing personnel) on 10/23/2020 at 1:30 p.m. confirmed the above findings. Staff A further revealed that there may be a page missing from the control and patient CA 125 test records from 9/20/2020 but could not locate it during the time of the survey.
D5461	CONTROL PROCEDURES CFR(s): 493.1256(d)(6)(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-- Perform control material testing as specified in this paragraph before resuming patient testing when a complete change of reagents is introduced; major preventive maintenance is performed; or any critical part that may influence test performance is replaced. (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 document control testing following calibration of the chemistry analyzer in September 2020. Findings include: 1) Review on 10/23/2020 of calibration records for the Tosoh AIA 360 analyzer revealed the last calibration was performed on 9/19/2020. 2) Review on 10/23 /2020 of control records for cancer antigen 125 (CA 125) performed on the Tosoh AIA 360 analyzer revealed no records of control testing performed on 9/19/2020 or on 9/20/2020 when at least 15 patient CA 125 tests were performed and reported. 3) Interview with Staff A (testing personnel) on 10/23/2020 at 1:30 p.m. confirmed the

	above findings. Staff A revealed since the patient test log included a full page of patient testing, there was likely a page missing from the log book that included the control testing (always placed first on the log page) and additional patient testing.
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 to perform and document corrective action when chemistry control results failed to meet manufacturer's assayed ranges in 2020. Findings include: 1) Review on 10/23/2020 of control testing from 8/23/2020 to 10/23/2020 for cancer antigen 125 (CA 125) revealed the assayed range for level 3 (lot 1912179C, expiration 1/31/2023) in use on the above dates, is 209.5 - 289.1 U/mL. Further review revealed the following control results for level 3: 8/23/2020 = 205.2 U/mL 9/6/2020 = 208.1 U/mL 10/4/2020 = 202.0 U/mL 10/10/2020 = 206.2 U/mL 2) Review on 10/23/2020 of patient test records for 8/23/2020, 9/6/2020, 10/4/2020, and 10/10/2020 revealed 41 patient CA 125 tests had been performed and reported. 3) Interview with Staff A (testing personnel) on 10/23/2020 at 1:30 p.m. confirmed the above findings. Staff A revealed the failed control testing had not been identified by testing personnel at the time of testing. Staff A further revealed that the laboratory does not review control testing to identify and correct failures in quality as they occur.
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 lack of written procedures and staff interview, the laboratory failed to establish and maintain procedures for monitoring the quality of analytic systems used for routine chemistry and hematology testing in 2018, 2019, and 2020. Findings include: 1) The laboratory lacked procedures for monitoring test systems used for cancer antigen 125 (CA 125) and complete blood count (CBC) testing in 2018, 2019, and 2020 requested by the surveyor at the time of the survey on 10/23/2020. 2) Interview with Staff A (testing personnel) on 10/23/2020 at 2:45 p.m. revealed the laboratory did not have a procedure to monitor and assess the quality of systems used for CA 125 and CBC testing.

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 routine chemistry and hematology testing performed in 2018, 2019, and 2020. Findings include: The laboratory director failed to review and sign proficiency testing (PT) reports and identify problems through evaluation of unacceptable results obtained for 6 of 6 chemistry PT events and 7 of 7 hematology PT events in 2018, 2019, and 2020. Refer to tag D6018. The laboratory director failed to ensure the quality control programs are maintained to assure quality of routine chemistry and hematology testing in 2019 and 2020. Refer to tag D6020. The laboratory director failed to ensure the quality assessment programs are established and maintained to assure quality of routine chemistry and hematology testing in 2018, 2019, and 2020. Refer to tag D6021.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory director failed to review and sign proficiency testing (PT) reports and identify problems through evaluation of unacceptable results obtained for 6 of 6 chemistry PT events and 7 of 7 hematology PT events in 2018, 2019, and 2020. Findings include: 1) Review on 10/23/2020 of the laboratory's American Proficiency Institute (API) PT records from 2018, 2019, and 2020 revealed 7 of 7 complete blood count (CBC) PT events failed to include the laboratory director's dated signature. Further review revealed the laboratory obtained unacceptable results for the following API Hematology / Coagulation events and no follow up was documented to identify the cause or correct the problem: 2019 Event 1 - white blood cell count - 80%; 2019 Event 2 - all CBC analytes - 0%; 2019 Event 3 - red blood count - 80%; 2020 Event 1 - hematocrit, hemoglobin, red blood count, monocyte differential - 80% (each analyte); 2020 Event 2 - white cell differential - 0% & hemoglobin - 80%; 2) Review on 10.23/2020 of the laboratory's API PT records from 2018, 2019, and 2020 revealed 2 of 6 cancer antigen 125 (CA 125) PT events failed to include the laboratory director's dated signature. Further review revealed the laboratory obtained unacceptable results for the following API Chemistry - Core (2020) events and no follow up was documented to identify the cause or correct the problem. 2020-Event 1 - 50% 2020-Event 3 - 0% 3) Interview with staff A (testing personnel) on 10/23/20 at approximately 12:00 p.m. confirmed the above findings.

	Staff A revealed that no follow up had been performed to identify why the laboratory obtained unacceptable results for the PT events listed above.
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 programs are maintained to assure quality of routine chemistry and hematology testing in 2019 and 2020. Findings include: 1) The laboratory failed to perform hematology calibration procedures in 2019 and 2020. Refer to tag D5437. 2) The laboratory failed to dcoument control procedures for cancer antigen 125 (CA 125) testing in September 2020. Refer to tag D5447. 2) The laboratory failed to document control procedures after calibration of the chemistry analyzer for CA 125 in September 2020. Refer to tag D5461. 3) The laboratory failed to perform and document corrective action when chemistry control results failed to meet manufacturer's assayed ranges in 2020. 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 the quality assessment programs are established and maintained to assure quality of routine chemistry and hematology testing in 2018, 2019, and 2020. Refer to tag D5791.