Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	30D1081393	03/04/2020
Name of Provider or Supplier	**Street Address, City, State**	
Elliot Hospital Point Of Care Testing	1 Elliot Way, Manchester, 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
D3003	FACILITIES CFR(s): 493.1101(a)(2) The laboratory must be constructed, arranged, and maintained to ensure contamination of patient specimens, equipment, instruments, reagents, materials, and supplies is minimized. This STANDARD is not met as evidenced by: Based on observation of the Surgical Day Care (SDC) i-STAT meter and staff interview, the laboratory failed to ensure the i-STAT meter was maintained to minimize contamination. Findings include: 1) Observation of the SDC i-STAT meter on 3/4/2020 at 8:50 a.m. revealed a piece missing from a corner of the meter's exterior. 2) Interview with Technical Consultant (TC1) on 3/4/2020 at 8:50 confirmed the above finding. 3) 4) Interview with Technical Consultant (TC2) on 3/4/2020 at 11: 00 a.m. revealed the SDC performed, on average, 1-2 prothrombin (PT/INR) tests per day using the i-STAT.
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: Based on observation of the Surgical Day Care (SDC) i-Stat meter, review of procedures, and staff interview, the laboratory failed to clean and maintain the SDC i-STAT meter used to perform 1-2 hematology tests per day. Findings include: 1) Review of the laboratory's procedure titled "I-STAT Testing" revealed, on page 15

	under Maintenance, instruction to "Clean the i-STAT with a Sani-Cloth between patient uses." 2) Observation of the i-STAT in SDC on 3/4/2020 at 8:50 a.m. revealed a red substance consistent with dried blood and a yellowish substance on the sides of the meter. 3) Interview with Testing Personnel (TP1) and Technical Consultant (TC1) on 3/4/2020 at 8:50 a.m. confirmed the meter was not clean. TP1 cleaned the exterior surface of the i-STAT at this time. 4) Interview with Technical Consultant (TC2) on 3 /4/2020 at 11:00 a.m. revealed the SDC performed, on average, 1-2 prothrombin (PT /INR) tests per day using the i-STAT. 5) This is a repeat deficiency from the initial certification survey completed on 9/28/2018.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on review of Surgical Day Care (SDC) laboratory refrigerator temperature logs and staff interview, the laboratory failed to retain the SDC refrigerator temperature log for January 2020. Findings include: 1) The SDC laboratory refrigerator temperature logs from July 2019 through February 2020 were requested by the surveyor on 3/4/2020. The laboratory failed to provide the SDC refrigerator temperature log for January 2020. 2) Interview with two Technical Consultants (TC1 and TC2) on 3/4/2020 at 11:00 revealed the laboratory was not able to locate the SDC laboratory refrigerator temperature log for January 2020.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on observation of Surgical Day Care's (SDC) laboratory refrigerator, review of refrigerator temperature logs and staff interview, the laboratory failed to document SDC refrigerator temperatures for 38 of 213 days in July 2019 through December 2019 and February 2020, the SDC refrigerator is used to store prothrombin (PT/INR) test cartridges and the SDC averages 1-2 patient PT/INR tests each day. Findings include: 1) Observation of the SDC laboratory refrigerator on 3/4/2020 at 9:00 a.m. revealed the PT/INR test cartridges for the i-STAT test system are stored in the refrigerator. 2) Review of the SDC laboratory refrigerator temperature logs from July 2019 through December 2019 and February 2020 revealed no temperatures were documented on the following [38] days: 7/26/2019, 8/2/2019, 8/5/2019, 8/31/2019, 9 /14/2019, 9/15/2019, 9/27/2019, 9/28/2019, 9/29/2019, 10/2/2019, 10/5/2019, 10/6 /2019, 10/16/2019, 10/26/2019, 10/30/2019, 11/1/2019, 11/2/2019, 11/3/2019, 11/23

	/2019, 11/24/2019, 11/28/2019, 11/29/2019, 12/4/2019, 12/7/2019, 12/8/2019, 12/11 /2019, 12/25/2019, 12/30/2019, 2/5/2020, 2/8/2020, 2/10/2020, 2/11/2020, 2/12/2020, 2/15/2020, 2/26/2020, 2/22/2020, 2/28/2020, and 2/29/2020. The laboratory failed to provide the SDC refrigerator temperature log for January 2020. 3) Interview with two Technical Consultants (TC1 and TC2) on 3/4/2020 at 11:00 a.m. confirmed the above findings. TC2 revealed the SDC performs on average 1-2 PT/INR tests per day, Monday through Friday.
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 review of Surgical Day Care (SDC) laboratory laboratory refrigerator temperature log and staff interview, the laboratory failed to follow procedures and document corrective action when the SDC refrigerator temperature fell outside the acceptable range on 2 of 31 days in October 2019. Findings include: 1) Review of the SDC laboratory refrigerator temperature log for October 2019 revealed the acceptable temperature range was 2-8 degrees Celsius (C). Further review revealed the temperature was 10 degrees C on 10/3/2019 and 9 degrees C on 10/4/2019. Corrective action procedures outlined on the bottom of the log sheet include a recheck of the temperature in one hour. Review of the corrective action for 10/3/2019 revealed the temperature was checked and recorded at 2:00 p.m., 8 hours after the initial temperature for the day was recorded at 6:00 a.m. There was no corrective action documented for 10/4/2019. 2) Interview with Technical Consultant (TC1) on 3/4/2020 at 11:00 a.m. confirmed the above finding.
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 review of the laboratory's quality control plan and quality assurance procedure and staff interview, the laboratory failed to follow quality assessment procedure to catch and correct failures identified in the analytic system for hematology testing in 2019 and 2020. Findings include: 1) Review of the laboratory's individualized quality control plan titled "ISTAT IQCP Study" revealed the following: "1. Document department temperature are in appropriate ranges on each of patient

	testing. The acceptable temperature ranges are noted on the temperature logs." and "2. Train testing personnel regarding...proper storage of testing components." 2) Review of the lab's procedure titled "Quality Assurance Monitoring" revealed the temperature records will be reviewed by the Point of Care Technical Specialist. 3) The laboratory failed to monitor the temperature records and identify days when temperatures were not documented and when corrective action procedures were not followed if the temperature was unacceptable. Refer to tags D5413 and D5781. 4) The laboratory failed to monitor i-STAT meters were maintained and cleaned to minimize contamination of equipment and protect individuals from biohazardous materials . Refer to tags D3003 and D3011. 5) Interview with Technical Consultants (TC1 and TC2) on 3/4/2020 at 11:00 a.m. confirmed the temperature logs were not reviewed and revealed maintenance of i-STAT meters located in SDC elsewhere within the hospital (under this CLIA certificate) are not checked.