Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D2173149	(X3) Date Survey Completed 12/07/2020
Name of Provider or Supplier Duly Health And Care - Lockport Ir	**Street Address, City, State** 1206 E 9th St - Ste 300, Lockport, IL	

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
D5301	TEST REQUEST CFR(s): 493.1241(a) The laboratory must have a written or electronic request for patient testing from an authorized person. This STANDARD is not met as evidenced by: Based on review the laboratory's procedure manual; patients' test reports; and interview with the laboratory director, the laboratory failed to have a written or electronic request for patient testing from an authorized person for its Activated Clotting Time test. Findings: 1. Review of the laboratory's procedure manual revealed that there were no written procedures that described how tests are ordered. 2. Review of 5 patients test reports revealed that there was no documentation to show that the tests were ordered from an authorized person for 5 of 5 reviewed. 3. On December 7, 2020 at 10:30 AM, the laboratory director confirmed the surveyor's findings.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) 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. This STANDARD is not met as evidenced by: Based on review of the laboratories policies and procedures manual; patients' test results; electronic records; and interview with the laboratory director, the laboratory failed to have a procedure manual that included the following: *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. Findings: 1. Review of the laboratory's procedure manaul revealed that there were no procedures that described the laboratory's process for reporting patients' test results. 2. On December 7, 2020 at 11:15 AM review of 5 patients' test results revealed 1 of 5 patients' test results was not entered into the patient chart and 1 of 5 patients' test result was not recorded in the location where laboratory tests were recorded. 3. On December 7, 2020 at 11:20 AM, review of electronic test records show that 1 of 2 missing patients' test results in finding #2 was recorded in the nurse's notes. 4. On December 7, 2020 at 11:30 AM, the laboratory director confirmed the surveyor's findings.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manual; quality control (QC) records; and interview with the laboratory director, the laboratory failed to establish the number, type, and frequency of testing control materials it established as specified in 493.1253(b)(3) for its Activated Clotting Time testing. Findings: 1. Review of the laboratory's procedure manual revealed that the laboratory developed an Individual Quality Control Plan (IQCP) based on the manufacture's recommendation of performing QC when new lots or shipments of QC were received and/or opened, and at least every 30 days. 2. On December 7, 2020 at 11:00 AM review of QC records revealed that testing personnel performed QC every two weeks instead of every 30 days per procedure manual. 3. On December 7, 2020 at 11:30 AM, the laboratory director confirmed the surveyor's findings.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(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 postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manual; patient testing logs; patients' test reports; quality assessments; and interview with the laboratory director, the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and correct problems in the post analytic systems of its Clotting Times as specified in 493.1291. Findings: 1. Review of the laboratory's procedure manual revealed that there was no written policy that describes the laboratory's process for assessing post analytic laboratory procedures. 2. The following information was recorded on the patient testing log. a. Date and Time b. Patient Name c. Test Result d. Epic Result Verified by 3. On December 7, 2020 at 11: 00 AM, the surveyor reviewed the patient testing log from which 5 patients names were selected. There was no documentation to show Epic results were verified for 1 of 5 patients records reviewed. 4. On December 7, 2020 at 11:15 AM review of the test results for the 5 patients selected from the testing log revealed that 1 of 5 patients' test results was not entered into the patient chart and 1 of 5 patients' test result was not recorded in the location where laboratory tests are recorded. The result was recorded in the nurse's notes. 5. There was no documentation to show that patients' test results were reviewed to verify that results were entered into the electronic record. 6. On December 7, 2020 at 11:30 AM, the laboratory director confirmed the surveyor's findings.