Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0669087	04/05/2018
Name of Provider or Supplier	**Street Address, City, State**	
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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
D5016	ROUTINE CHEMISTRY CFR(s): 493.1210 If the laboratory provides services in the subspecialty of Routine Chemistry, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493. 1267, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on chemistry test quality control records review and interview with the laboratory director on April 5, 2218, it was determined that the laboratory failed to ensure compliance with the analytic system requirements for troponin tests since September 2018. Refer to D5403 - No written procedures for rechecked of critical values Refer to D5447- The laboratory did not include any control material each day of testing.
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 laboratory tests procedure manual, interview with the laboratory supervisor, the laboratory general supervisor , three medical technologists (MT"s) , review of the troponin logbook and final test reports on April 5, 2018 at 11: 50 AM, it was found that the laboratory did not have written procedure for tests rerun due to critical values or any other situation. The findings include: a. The troponin patient test results logbook was reviewed on April 5, 2018 at 11:50 AM. The logbook included a test value of over 0.05 ng/ml as a reminder of a critical value. b. The laboratory director, the general supervisor and MT"s 1, 2 and 3 were interviewed about the procedures of critical values. All of them stated that the guideline was: that all critical values must be rerun (to rechecked the initial value) and then must be informed to the physician in charge. c. Review of troponin patient's test logbook showed that four (4) patient's had critical values over 0.05 ng/ml, however only one of them was rechecked. d. Review of the patient's final test showed that all the four test results included a note of: ****CRITICAL VALUE****RECHECKED*** e. Review of the laboratory procedure manual did not include any written procedure for rerun of critical tests values. d. The laboratory director and the general supervisor stated that they were not aware about the missing guideline in the procedure manual.
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 review of quality control and patient's logbook, interview with the laboratory director and interview the laboratory general supervisor on April 5, 2018 at 11:00 AM, it was found that the laboratory did not include two levels of control material when the laboratory performed patient's troponin tests. The findings include: a. The laboratory director and the laboratory general supervisor stated on April 5, 2018 at 11:00 AM , that they performed Troponin tests by the Alere Triage Meter since September 28, 2017. Troponin tests by the Alere Triage Meter is a moderate complexity test. b. During interview the general supervisor stated that they run two levels of control material once a month and with a new reagent lot number. c. The quality control and patient logbook was reviewed, showing that the laboratory included two levels of control material , once a month, as the laboratory general supervisor stated during her interview. d. Since September 27, 2018 to February 24, 2018 the laboratory processed and reported 102 troponin patient samples. e. The laboratory did not include any control material on 58 out of 63 days of patient runs.

	The laboratory reported ninety-seven (97) patient samples during those dates. f. The laboratory director and the general supervisor stated that the control material was an expensive one, so they were not able to purchase enough control material.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on review of quality control records, patient's troponin tests logbook and personnel records files on April 5, 2018, it was determined that the laboratory director did not fulfill her responsibilities regarding to troponin quality control, personnel records not procedure manual written protocols. Refer To D6093, D6102 and D6106
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on chemistry control records review and interview with the laboratory director on April 5, 2018, at 11:00 AM it was determined that the laboratory did not make sure that control materials were included when patient's samples were tested for troponin tests since September 2017. Refer to D5447.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on personnel records review, laboratory director and technical supervisor interview at 9:00 AM on April 5, 2017, it was determined that the laboratory director failed to ensure that the testing personnel, prior to testing patients' specimens, had the appropriate training. The finding includes: a. Review of the following testing personnel files, who performed moderate and high complexity tests, showed that no training was accomplished prior to test and report patient's samples: i. Medical Technologist (MT) # 6569- the laboratory director and the technical supervisor stated that MT was a part time employee. ii Medical Technologist # 5194 - the laboratory director and the technical supervisor stated that MT worked only on Saturday from 3: 00 to 11:00 PM

D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. This STANDARD is not met as evidenced by: Based on laboratory test procedure manual review and interview with the laboratory director on April 5, 2018 at 11:00 AM, it was determined that the laboratory failed to ensure that written procedures for patient' s samples rerun were included in the procedure manual. The finding includes: a. The laboratory performed moderate and high complexity tests. a. Review of the procedure manual showed that no written procedures or guidelines were included regarding rerun of patient samples with critical results not any other cause. b. The laboratory director stated that procedures for communication of critical values were included not for the rerun of patient samples. Refer to D5403.
D6177	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1495(b)(3) Each individual performing high 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 quality control records review, patient's troponin logbook and testing personnel interview on April 5, 2018 at 12: 05 PM, was determined that testing personnel failed to follow quality control and patient rechecked procedures. Refer to D 5403 and D5447.