Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D0893846	04/23/2019
Name of Provider or Supplier	**Street Address, City, State**	
Bolingbrook Immediate Care Center	130 N Weber Road, Bolingbrook, 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
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 laboratory records and interview with testing personnel (TP) #15; the laboratory failed to outline all components of the d-dimer test procedure. Findings Include: 1. Review of the policy and procedure manual identified the procedure, "Triage D-Dimer Operation", which failed to outline the following required components of a test procedure: a. Control procedures. b. Corrective action to take when control results fail to meet the laboratory's criteria for acceptability. 2. During survey date 04-23-2019, at 4:40 pm, the above findings were confirmed by TP #15.

D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: A. Based on direct observation, review of laboratory records, and interview with technical consultant (TC) #1; the laboratory failed to demonstrate it can obtain performance specifications comparable to those established by the manufacturer for troponin-I testing on the i-Stat analyzer prior to reporting patient test results. Findings Include: 1. Direct observation of laboratory testing equipment on 04-23-2019, at 11:30 am, identified a i-Stat analyzer and cartridges for troponin-I testing. 2. Review of laboratory documentation found no verification study was performed by the laboratory to demonstrate the laboratory can obtain performance specification comparable to those established by the manufacturer for accuracy, precision, reportable range, and verification of the manufacturer's reference intervals. 3. Review of the non-waived test volume worksheet indicated 893 patients were tested for troponin-I from March 2018 to March 2019. 4. On survey date 4-23-2019, at 12:35 pm, the above findings were confirmed by TC #1. B. Based on direct observation, review of laboratory records, and interview with technical consultant (TC) #1; the laboratory failed to demonstrate it can obtain performance specifications comparable to those established by the manufacturer for d-dimer testing on the Triage MeterPro prior to reporting patient test results. Findings Include: 1. Direct observation of laboratory testing equipment on 04-23-2019, at 11:30 am, identified a Triage MeterPro and cartridges for d-dimer testing. 2. Review of laboratory documentation found no verification study was performed by the laboratory to demonstrate the laboratory can obtain performance specification comparable to those established by the manufacturer for accuracy, precision, reportable range, and verification of the manufacturer's reference intervals. 3. Review of the non-waived test volume worksheet indicated 533 patients were tested for troponin-I from March 2018 to March 2019. 4. On survey date 4-23-2019, at 12:35 pm, the above findings were confirmed by TC #1.