Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	15D2141634	06/25/2018
Name of Provider or Supplier	**Street Address, City, State**	
St Vincent Hospital And Health Care Center, Inc	8602 North Allisonville Road, Indianapolis, IN	

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 record review and interview, the laboratory failed to include alert values for one of three procedures reviewed ("Triage Cardiac Panel Test"). Findings Include: 1) Review of policy titled, "TRIAGE CARDIAC PANEL TEST FOR EDTA WHOLE BLOOD", laboratory director approval, 4/20/18 covered the procedures for testing, "used as an aid in the diagnosis of myocardial infarctions. The test panel includes; cardiac proteins, CK-MB (creatinine kinase muscle/brain), myoglobin, and troponin." There was no protocol for reporting life threatening result, panic values, or alert values. 2) Medical record review indicated PT-11 was tested on the Triage analyzer

	for a cardiac panel and had an elevated Troponin level of 1.88 ng/mL (nanograms per milliliter) on 5/17/18 at 7:43 pm. This elevated level was not communicated to the appropriate healthcare provider (refer to D-5813). 3) In interview on 6/25/18 at 11:05 am, SP-7 confirmed the laboratory did not have protocols for life threatening result, panic values, and alert values listed in the above policy.
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: Based on document review and interview, the laboratory failed to demonstrate comparable performance specifications to that of the manufacturers for two of three laboratory test systems reviewed ("Alere Triage Meter Pro" and "Medonic"). Findings Include: 1) Review of the following performance specification data indicated they were performed by the manufacturers: a. Alere Triage Meter Pro validation documentation indicated, "St Vincent Neighborhood Castleton, Indianapolis IN Triage Cardiac Panel, BNP Test, and D-Dimer Test Performance Verification Data Analysis Performed For SP-7 (name redacted from quote) POCC 3/7/18." This is a quote from the manufacturer stating they performed the verification for St Vincent Neighborhood Castleton, specifically for SP-7. (BNP -Brain Natriuretic Peptide) b. Medonic validation documentation indicated, "...Dear Laboratory: Enclosed are the evaluations for the method validation studies for your new Medonic M Series hematology analyzer...", signed by SP-15 (Manufacturer Rep). 2) Medical record review indicated the following patients were tested on the Triage and Medonic analyzers: PT-1=Triage 6/18/18 PT-2=Triage 5/11/18 PT-3=Medonic 6/21/18 PT-4=Medonic 5/28/18 PT=patient 3) In interview on 6/25/18 at 10:49 am, SP-7 confirmed the laboratory failed to demonstrate that it can obtain performance specifications comparable to that of the manufacturer for the two testing platforms listed above (Alere Triage Cardiac Pro and Medonic Hematology analyzer).
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: Based on document review and interview, the laboratory failed to follow its

	established protocols for maintenance and function checks on two of three analyzers maintenance logs reviewed (Medonic and I-Stat). Findings Include: 1) Review of policy titled, "Complete Blood Count with Three Part Differential Using the Medonic M-series", "7/2017", laboratory director sign off, 4/20/18 indicated "... MAINTENANCE A. Daily 4. Clean the Open Tube sample probe using an alcohol wipe. 5. Remove possible traces of salt crystals or blood on the Open Tube probe, probe rinse cup, Pre-dilute probe, and around the top of the Cap Pierce using a paper tissue with a disinfection solution. 6. Clean the outside of the instrument with a soft cloth and DI water if needed." 2) Review of policy titled, "I-STAT", "7/2017", laboratory director approval on 4/20/18, indicated "...D. CLEANING and DISINFECTING the i-STAT ANALYZER: 1. Clean the display screen with a soft dry Kim-Wipe. Clean the case using a Sani-cloth. Rinse using a Kim-Wipe moistened with water. Dry completely. DO NOT IMMERSE the analyzer in liquids..." 3) Medical record review indicated the following patients were tested on the Medonic M-Series and I-Stat analyzers: PT-3=Medonic 6/21/18 PT-4=Medonic 5/28/18 PT-7=I-Stat 5/17/18 PT-8=I-Stat 6/24/18 PT-9=I-Stat 6/19/18 PT-10=I-Stat 5/10/18 4) In interview on 6/25/18 at 1:25 pm, SP-7 confirmed there was no documentation indicating the above policies were being followed for maintenance and function checks.
D5813	TEST REPORT CFR(s): 493.1291(g) The laboratory must immediately alert the individual or entity requesting the test and, if applicable, the individual responsible for using the test results when any test result indicates an imminently life-threatening condition, or panic or alert values. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to alert the responsible individual of an alert value for 1 of 11 patient test reports (PT-11) reviewed. Findings Include: 1) Policy titled, "Critical Results Reporting Policy," "REFERENCE NUMBER: IN-SVNH-LS-Critical Results, " "EFFECTIVE DATE: 7/1/2017," signed by the laboratory director on 4/20/18 states, ...A. Critical results shall be reported to the individual ordering the test and/or the physician or other healthcare provider responsible for the patient, as appropriate, by the patient's physician or that provider's supervisor immediately upon receipt of the test result..." 2) Review of patient's test report (PT-11), indicated a flagged Troponin (cardiac marker) result of 1.88 ng/mL (nanograms per milliliter) on 5/17/18 at 7:43 pm and a second result of 0.59 ng/mL on 5/17/18 at 9:46 pm. The results were indicated as flagged alert values in the following software programs: a. "Alere RALS" interfacing computer software program for the laboratory testing analyzers. Flagged as "(E) ?-0.05". b. Patient electronic record accessed by nursing staff and other authorized healthcare officials. Flagged as a red arrow pointing upward next to the result. 3) In interview on 6/25/18 at 3:50 pm, SP-7 confirmed the above elevated Troponin results and had no documentation that the information was communicated to the responsible healthcare provider when an alert value was indicated per policy.