Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D1018992	01/24/2018
Name of Provider or Supplier	**Street Address, City, State**	
Lillehei Clinical Research Unit	516 Delaware St Se Room 1-320 Pwb, Minneapolis, MN	

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 observation, document review and interview with laboratory personnel, the laboratory failed to ensure the reportable range obtained during performance verification of a new chemistry analyzer was accurate in the procedure manual. Findings are as follows: 1. The laboratory performed Creatine Kinase - MB (CK-MB) testing under the specialty of Chemistry as confirmed by Testing Personnel 1 (TP1) during a tour of the laboratory on 01/24/18 at 12:30 p.m. 2. A Siemens Stratus CS chemistry analyzer was observed as present and available for use during the tour of

	the laboratory. The laboratory completed performance verification (PV) activities and began CK-MB testing on patient specimens using this analyzer in November 2017 as indicated by TP1 during the tour. 3. The CK-MB reportable range found in the Quantification of Creatine Kinase MB (CK-MB) in Heparinized Plasma on the Stratus CS STAT Fluorometer Analyzer procedure did not reflect the actual reportable range values obtained by the laboratory during the PV. See below. Analyte PV Procedure CK-MB 0.3-116.0 0.3-150 4. In an interview on 01/24/18 at 3:20 p.m., TP1 confirmed the above finding and stated the laboratory had used the manufacturer's analytical measurement range for CK-MB as the reportable range in procedure.