Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D0697215	01/30/2018
Name of Provider or Supplier	**Street Address, City, State**	
Rml Specialty Hospital Chicago	3435 W Van Buren St, Chicago, 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
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 the surveyor's review of the laboratory records, manuals, and an interview with the laboratory administrator, the laboratory failed to document a complete IQCP for testing performed in the subspecialty of Routine Chemistry. Findings: 1. A review of the IQCP documentation showed that the laboratory's plan does not include a quality control (QC) plan which defines the reduced QC procedure to be performed on the new Blood Gas test system in-use, prior to testing patients. 2. The records reveal that patient testing began on 03/31/2016. 3. The Quality Assessment (QA) plan reviewed does not include a routine review of the manufacturer's instructions for the Blood Gas Cartridges used for patient testing. 4. On a Validation survey conducted on 01/30/2018 at 1:15PM, the laboratory administrator and staff confirmed the above findings.
D5779	CORRECTIVE ACTIONS CFR(s): 493.1282(a) Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that

	ensures accurate and reliable patient test results and reports. This STANDARD is not met as evidenced by: Based on the surveyor's review of the laboratory's records, manuals and an interview with the laboratory staff, the laboratory failed to follow corrective action policies and procedures when necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports. Findings: 1. The laboratory manuals states that calibration verifications are to be performed every six months on the 2 I-stat Blood Gas analyzers used for patient testing. 2. Review of the quality control and maintenance logs revealed that the calibration verifications were performed on the following dates: a) Analyzer A - 04 /15-22/2016; 11/10/2016; and 10/26/2017 b) Analyzer B - 04/15-22/2016; 11/10 /2016; and 10/26/2017 3. The Corrective action submitted for the missed calibration verification is an investigation worksheet from CAP (College of American Pathologists) proficiency testing (PT) program, which is used for PT failures or incidences. The laboratory did not use the corrective action procedure in it's manual. No documentation was provided as evidence the laboratory performed an investigation to access the following: a). Was quality testing maintained from 11/11 /2016 through 10/25/2017; b). If applicable, were possible patients affected identified; and c). How to prevent re-occurrence of the missed calibration verification. 4. On a Validation survey conducted on 01/30/2018 at 1:15PM the laboratory administrator and staff confirmed the above findings.