Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2084189	11/07/2018
Name of Provider or Supplier	**Street Address, City, State**	
Surepoint Emergency Center Chisholm Trail	7445 Oakmont Blvd, Fort Worth, TX	

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 review of the laboratory's Individualized Quality Control Plan (IQCP) procedure and interview with facility personnel, the laboratory failed to identify the frequency and potential impact for each potential source of error identified in the laboratory's Risk Assessment (RA) for the Abaxis Piccolo MetLac12 cartridge. The findings included: 1. Conducting the Risk Assessment: To conduct a risk assessment, the laboratory must identify the sources of potential failures and errors for a testing process, and evaluate the frequency and impact of those failures and sources of error on test quality. 2. Review of the Risk Assessment portion of the IQCP for the Abaxis Piccolo MetLac12 cartridge, signed by the laboratory director on 09/08/2016, included potential sources of error and mitigation strategies. The Risk Assessment DID NOT include the frequency with which the laboratory defined potential sources of error had occurred or were likely to occur. As a potential risk, the laboratory identified "Specimen: Preanalytic: Wrong patient drawn". The laboratory did not document the frequency the laboratory had collected a specimen from the wrong patient or evaluate how likely this event would occur. 3. The Risk Assessment DID NOT include an assessment of the potential impact on patient results for each laboratory defined potential source of error. The lab defined "The specimen cannot be

	in the cartridge longer than 10 minutes prior to inserting the analyzer for testing" as a potential risk of error. The laboratory did not define the potential impact on patient testing and test quality when testing personnel have exceeded the 10-minute threshold. 4. In an interview at 15:13 hours on 11/07/2018 in the break room, the Facility Manager stated that the laboratory monitored potential sources of error through quality assurance activities but had not defined the frequency and impact of each source of error as part of the IQCP risk assessment.