

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2125361	(X3) Date Survey Completed 04/23/2019
Name of Provider or Supplier Surepoint Emergency Center Azle	Street Address, City, State 611 Northwest Parkway, Azle, 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
D5411	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.</p> <p>This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions for the Alere iCassette Drugs Screen , revealed the laboratory failed to follow the manufacture's instruction when a positive result is obtained. The findings were as follows: a. A review of the manufacturer's instructions for the Alere iCassette Drugs Screen states " when a positive result is obtained the specimen must be confirmed" b. Based upon interview with Technical Consultant #1 (from the CMS form 209) on April 23, 2019 at 1100 hrs stated " the laboratory does not send the positive drug screen for confirmation unless the physician orders The laboratory performs from January 1, 2019 to April 23, 2019 8 patients 4 of which had positive test and were not sent off for confirmation. .</p>