

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0585635	(X3) Date Survey Completed 03/14/2019
Name of Provider or Supplier Adventist Health Tulare	Street Address, City, State 869 North Cherry St, Tulare, CA	
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 laboratory's proficiency testing (PT) result reports, quality control documents, an interview with the technical superior and laboratory personnel and thirteen (13) random patient sampling (including urine drug abuse testing) reviewed from 10/19/2018 to 03/14/2019, it was determined that the laboratory failed to follow the manufacturer's instructions in a manner that provides test results within the laboratory's stated performance specifications for urine drug screen testing using the Bio-Rad TOX/See moderate complexity test kit. The findings included: a. The laboratory performed urine drug screen testing using the Bio-Rad moderate complexity test kit. The manufacturer's product insert stated under LIMITATIONS, "1. The TOX/See Drug Screen Test provides only a qualitative, preliminary, analytical result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method." b. On 03/14/2019 (survey date) 14:00, the technical supervisor and laboratory personnel confirmed that the patients' electronic medical records (EMR) did not specify the manufacturer's limitations and that a secondary analytical method assay was performed on the patient's final report for urine drug screen test results as mandated in the manufacturers package insert instructions. No documentation could be retrieved that confirmatory drug of abuse test was performed consistently on every urine drug screening test as required by the manufacturer. c. Based on the laboratory's annual testing provided on 03/18/2019, the laboratory analyzed and reported 557 urine drug screen test results.</p>