Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 17D0450716	(X3) Date Survey Completed 04/30/2018
Name of Provider or Supplier Newman Regional Health	**Street Address, City, State** 1201 West 12th Avenue, Emporia, KS	
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	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) 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. This STANDARD is not met as evidenced by: A review of manufacture's package QuickVue H Pylori Test under limitations states this assay has not been established for patients under 18 years of age revealed the laboratory failed to follow manufactures instructions. Findings were as follows a. Based upon a review of the H Pylori Test revealed the laboratory performed 16 patients under the age of 18 01/01/2016 through 12/31/2017 52 patients were tested. Therefore, the accuracy of the testing cannot be verified.