

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 17D0700241	(X3) Date Survey Completed 10/18/2018
Name of Provider or Supplier Sedan City Hospital	Street Address, City, State 300 North Street, Sedan, 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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on lack of documents and interview with the laboratory manager at 1:40 pm on October 18, 2018, the laboratory failed to have and follow policies and procedures to assess the technical consultant's competency.</p>
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: Review of 2017 Sysmex CA-600 test system records and manufacturer's instructions, Dade Innovin package inserts, interview with lab manager, and direct observation reveals that the laboratory failed to follow the manufacturer's instructions for test system operation. Findings include: 1. The laboratory reports an INR ratio which is calculated using the ISI value of the reagent currently in use. According to the package insert for Dade Innovin, lot 549708 with expiration date 2/23/2020, the correct ISI value is 1.00. An incorrect value of 0.98 was observed in the Sysmex CA-600 coagulation analyzer computer. Innovin lot 549708 was put into use September</p>

2017. 2. At the time of the survey, the lab failed to provide complete documentation of the normal patient mean study for the new lot of Innovin put into use during September 2017. 3. The above information was confirmed by Lab Manager and testing personnel #2, refer to Testing Personnel Report (CMS-209), at 13:40 on October 18, 2018.