

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 25D2227002	(X3) Date Survey Completed 05/18/2022
Name of Provider or Supplier Tate County Hospital Db a Highland Hills Medical Ct	Street Address, City, State 401 Getwell Dr, Senatobia, MS	
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 Sysmex CA-600 coagulation system manufacturer operator's manual, coagulation quality control (QC) records from 6/30/21 through 5/18/22, and confirmation with the general supervisor at 5:00 p.m. on 5/18/22, the laboratory did not establish a normal patient mean (NPM) when changing to a new lot of Prothrombin reagent (Innovin) as required by the manufacturer's instructions. Both the NPM and ISI values are used to calculate the INR (international normalized ratio) which is reported as part of the Prothrombin Time results. Findings include: 1. According to the CA-600 manufacturer's instructions, the NPM has to be entered into the analyzer along with the ISI value (assigned to each specific Innovin lot) in order for the analyzer to calculate an accurate patient INR (international normalized ratio) which is reported with the Prothrombin Time result. 2. Based on review of the Coagulation QC records from 6/30/21 through 5/18/22, there was no documentation of the start date for Innovin lot # 549763 (expiration date 11/28/22) which was in use the day of survey. 3. Based on observation of the coagulation instrument, the following values were entered for the INR calculation: a. ISI value of 1.01. (assigned for Innovin lot # 549763). b. Innovin lot # 549786 (expiration date 9/24/23) which has an assigned ISI value of 1.05. 4. There was no documentation available the day of survey to indicate that the laboratory had established a NPM (normal patient mean) with the current lot number of Innovin (549763) per the manufacturer's instructions. 4. Interview with the laboratory manager at 5:00 p.m. on 5/18/22 confirmed that when Innovin Lot# 549763 was put into use, the NPM (normal patient mean) was not</p>

established. The ISI value was changed in the instrument, but the lot number of Innovin was not. The manager was unable to give a definite timeframe other than 3-4 months ago. 5. According to the volume form and QC records, approximately 350 patient Prothrombin Times had been tested and resulted during this time period.