Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	25D0029591	05/30/2019
Name of Provider or Supplier	**Street Address, City, State**	
Trace Regional Hospital	1002 E Madison St, Houston, 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	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: Based on review of Sysmex CA-500 coagulation system manufacturer operator's manual, coagulation quality control (QC) records from 9/1/17 through day of survey, 5 /30/19, and confirmation with staff at 11:00 am on 5/30/19 the laboratory did not establish a normal patient mean (NPM) nor enter the correct ISI (International Sensitivity Index) when changing to a new lot of Prothrombin reagent (Innovin) as required by the manufacturer's instructions. Both NPM and ISI are used to calculate the INR (international normalized ratio) which is reported as part of the Prothrombin Test results. Findings include: 1. According to the CA-560 manufacturer's instructions, the NPM has to be entered into the analyzer along with the appropriate ISI value in order for the analyzer to calculate an accurate patient INR (international normalized ratio) which is reported with the Prothrombin result. 2. Based on review of the Coagulation QC records from 9/1/17 through 5/30/19 there was no documentation of when the Innovin reagent (lot # 539394 expiration date 8/18/19) in use on the day of survey, was started. 3. Based on observation of the coagulation instrument, the ISI value entered in the Sysmex CA-500 on the day of survey was 0.96. The ISI value of Innovin Lot #539394, in use on the day of survey, is 1.02. 4. There was no documentation available the day of survey to indicate the laboratory had established a NPM (normal patient mean) with the new lot number of Innovin per manufacturer's instructions. 5. Interview with the laboratory manager confirmed that when Innovin Lot # 539394 was put into use, the NPM was not established nor was the ISI value changed in the CA-560. 6. According to the volume form and QC records,

	approximately 496 patients' PT results had been tested and resulted during this time period.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of chemistry laboratory records from last survey 6/7/19 through the day of this survey, 5/30/19, and confirmation with laboratory manager at 5:00 pm on 5 /29/19, the laboratory failed to perform calibration verification on the Siemens Dimension EXL-LM chemistry analyzer every 6 months for sodium, potassium, chloride and the drugs of abuse panel (cocaine, THC, barbiturates, benzodiazepine, opiates, PCP and amphetamines). Findings include: 1. Review of Siemens Dimension EXL-LM calibration verification records revealed that a calibration verification was not performed on Sodium (NA), Potassium (K), and Chloride (CL) or the drugs of abuse panel every 6 months. The laboratory did not perform the calibration verifications on the NA, K and CL analytes due for 2017. The laboratory did not perform the 2nd calibration verification due in December 2017 for the drugs of abuse panel (cocaine, THC, barbiturates, benzodiazepine, opiates, PCP and amphetamines). These chemistry tests have only 1 or 2 calibration points and therefore require calibration verification to be performed every 6 months to verify the laboratory's reportable range. 2. During an interview at 5:00 pm on 5/29/19, the laboratory manager confirmed that semiannual NA, K and CL calibration verifications due in 2017 were not performed. The laboratory manager also confirmed that calibration verification due in 12/17 for the drugs of abuse panel was not performed by the laboratory.