

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 25D0704217	(X3) Date Survey Completed 11/20/2020
Name of Provider or Supplier Tyler Holmes Memorial Hospital	Street Address, City, State 409 Tyler Holmes Drive, Winona, 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 Abbott Cell Dyn Ruby Hematology Analyzer operator's procedure manual in use the day of survey and hematology control records and confirmation by the technical consultant (TC) at 11:00 am on the day of survey, 11/20/20, the laboratory failed to follow the manufacturer's instructions for the assay verification process for the quality control (QC) material. Findings include: 1. The Abbott Cell Dyn Ruby hematology operator's manual states that each new lot of control material should be analyzed in parallel with current lots prior to the expiration date of the current QC. The lab should verify the values of each new control lot by running each level of control in triplicate along with replicate QC specimens or the old control when still in date. The new QC should be run twice a day for five days to establish a mean to verify that the new lot yields the expected results in the manufacturer's package insert. 2. Review of the hematology control records from the last survey on 8/1/18 through 11/20/20 revealed the following lot numbers of hematology control had been put in use since last survey: 8169 (L,N,H), 8225 (L,N,H), 9028 (L,N,H), 9308 (L,N,H), 9364 (L,N,H), 0055 (L,N,H), 0111 (L,N,H), 0167 (L,N,H), 0223 (L,N,H). These lot numbers of QC material were put into use with no assay verification performed. 3. Interview with the TC on the day of survey at 11:00 am revealed no assay verification was being performed before putting a new lot number of QC into use on the Cell Dyn Ruby hematology analyzer according to the manufacturer's instructions.</p>