

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 25D0029746	(X3) Date Survey Completed 08/16/2024
Name of Provider or Supplier Copiah County Medical Center	Street Address, City, State 27190 Hwy 28, Hazlehurst, 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
D5421	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on review of verification of performance specifications for the Ortho Clinical Diagnostics Vitros XT 7600 Integrated System, put in use for patient testing on 7/30/2024, and the patient Specimen Log, the laboratory failed to verify accuracy, precision and reportable range for two tests of thirty-eight, performed on the Vitros XT Integrated System, before reporting test results on a total of twenty-four patients. Findings include: 1. Review of verification of performance specifications for the Ortho Clinical Diagnostics Vitros XT 7600 Integrated System and the patient Specimen Log, from 7/30/2024 through 8/16/2024, revealed the laboratory failed to verify accuracy, precision, and reportable range for phosphorus before reporting test results for the following twenty-three patients: 8/01/2024--Patients #177191, #175008. 8/02/2024--Patients #163788, #149406, #166640, #178843, #151469, #151588. 8/04/2024--Patients #177952, #181212, #139768. 8/05/2024--Patients #175008, #154183. 8/06/2024--Patient #140140. 8/07/2024--Patients #163584, #157265. 8/08/2024--Patients #141599, #175008. 8/12/2024--Patients #175008, #138505. 8/13/2024--Patient #173694. 8/14/2024--Patient #152284. 8/15/2024--Patient #175008. 2. Review of verification of performance specifications for the Ortho Clinical Diagnostics Vitros XT 7600 Integrated System and the patient Specimen Log, from 7/30/2024 through 8/16/2024, revealed the laboratory failed to verify accuracy,</p>

precision, and reportable range for acetaminophen before reporting test results for Patient #142289 on 8/10/2024.