

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 16D0387141	(X3) Date Survey Completed 08/06/2026
Name of Provider or Supplier Monroe County Hospital	Street Address, City, State 6580 165th Street, Albia, IA	
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
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) (d)(3)(i) Each quantitative procedure, include two control materials of different concentrations; This STANDARD is not met as evidenced by: Based on review of Ortho Vitros 5600 chemistry quality control (QC) records, the laboratory's Quality Control Policy, and confirmed by interview with General Supervisor #1 (GS #1) at 9:40 am on 08/06/2026, the laboratory failed to perform two levels of QC at least once each day of patient testing for 1 out of 31 days reviewed from 03/01/2026- 03/31/2026 for the following analytes: glucose, total protein, albumin, chloride, potassium, sodium, carbon dioxide, creatinine, blood urea nitrogen, calcium, total bilirubin, aspartate aminotransferase (AST), alkaline phosphatase, alanine aminotransferase (ALT), uric acid, and iron. The findings include: 1. The laboratory performs chemistry testing on an Ortho Vitros 5600 instrument. 2. For chemistry testing, the laboratory's Quality Control Policy stated, "Two levels of control material will be performed each morning after all maintenance procedures have been performed." 3. On 03/11/2026, the laboratory performed patient chemistry testing on the Ortho Vitros 5600 instrument, but only ran the Biorad Multiqual 2 control for the following analytes: glucose, total protein, albumin, chloride, potassium, sodium, carbon dioxide, creatinine, blood urea nitrogen, calcium, total bilirubin, AST, alkaline phosphatase, ALT, uric acid, and iron. 4. The laboratory performed a total of 22 patient tests for the following analytes on 03/11/2026: glucose, total protein, albumin, chloride, potassium, sodium, carbon dioxide, creatinine, blood urea nitrogen, calcium, total bilirubin, AST, alkaline phosphatase, and ALT. In addition, the laboratory performed 1 uric acid and 2 iron patient tests on 03/11/2026. 5. At the time of the survey, GS #1 confirmed the laboratory failed to perform two levels of QC at least once each day of patient testing for the analytes listed above on 03/11/2026.