

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 17D0690699	(X3) Date Survey Completed 03/28/2023
Name of Provider or Supplier Mcpherson Hospital	Street Address, City, State 1000 Hospital Drive, Mcpherson, KS	
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 the review of the performance verification for ferritin, vitamin B12, and folate performed on the Vitros 5600 chemistry analyzer, and interview with technical consultant (TC) #1, the laboratory failed to verify the patient normal values for ferritin, vitamin B12, and folate were appropriate for the laboratory's patient population prior to reporting patient test results. Findings: 1. Request was made to review the performance verifications for the ferritin, vitamin B12, and folate performed on the Vitros 5600 chemistry analyzer serial number J5600-1999. 2. Review of the performance verification revealed no normal range value verification. No acceptability of the manufacturer's stated normal ranges statement was present. 3. TC #1 stated, and documentation confirmed patient testing began 10/23/22. A total of 629 ferritin, 779 B12, and 140 folate patient results were reported 10/23/22 to 3/28/23 for 3 of 3 analytes. 4. Interview with TC #1 on 3/28/23 at 1:25 p.m. confirmed, the laboratory failed to verify the patient normal values for ferritin, vitamin B12, and folate were appropriate for the laboratory's patient population prior to reporting patient test results.</p>
D6053	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)</p>

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

Based on review of CMS form 209, competencies, patient test records, and interview, the technical consultant (TC) failed to document competency by direct observation of routine patient test performance, and assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples at least semiannually during the first year the individual tests patient specimens for 7 of 10 moderate complexity testing personnel (TP). Findings: 1. Review of the site's CMS for 209 for personnel revealed 10 new moderate complexity TP since last survey that had performed non-waived testing for 6 months. 2. Review of personnel 6 month competency records revealed 7 of 10 competencies lacked documentation of direct observation of routine patient test performance, and assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples for TP #14, TP#15, TP#18, TP#19, TP#20, TP#21, and TP#22 3. Review of patient test records revealed 864 test results for pH, pO₂, and pCO₂ had been reported from 7/1/21 to 3/28/23 by the 7 TP listed in item #2. 4. Interview with the TC #1 on 3/28/23 at 9:05 a.m. confirmed, the TC failed to document competency by direct observation of routine patient test performance, and assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples at least semiannually during the first year the individual tests patient specimens for 7 of 10 moderate complexity TP.