

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 17D0452504	(X3) Date Survey Completed 12/14/2018
Name of Provider or Supplier Mcperson Medical And Surgical Associates	Street Address, City, State 1000 Hospital Drive Building 3, 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
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on review of chemistry quality control (QC), hematology QC and interview with the technical supervisor the laboratory failed to retain QC records for at least 2 years. Findings: 1. Review of chemistry analytes beta human chorionic gonadotropin, vitamin B12, Ferritin, Free T4, PSA and thyroid stimulating hormone QC showed no instrument printouts or way to access QC in computer for the last 2 years. 2. Review of hematology complete blood count QC showed no instrument printouts or way to access QC in computer for the last 2 years. 3. Interview with the technical supervisor on December 14, 2018 at 11:30 AM confirmed the laboratory could not provide QC for review for chemistry analytes beta human chorionic gonadotropin, vitamin B12, Ferritin, Free T4, PSA, thyroid stimulating hormone and hematology complete blood count for the last 2 years.</p>
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 Beckman Coulter Access 2 chemistry analyzer validation and interview with the technical supervisor on December 14, 2018 at 11:30 PM confirmed the laboratory failed to verify that the manufacturer's reference intervals (normal ranges) are appropriate for the laboratory's patient population.</p>
<p>D6076</p>	<p>LABORATORY DIRECTOR CFR(s): 493.1441</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on review of quality control and interviews, the director failed to provide overall management and direction; failed to ensure that quality control was adequate (refer to D6093); failed to ensure quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur (refer to 6094).</p>
<p>D6093</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p> <p>The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.</p> <p>This STANDARD is not met as evidenced by: Based on review of chemistry and hematology quality control (QC) and interview with the technical supervisor the laboratory director failed to ensure QC was within acceptable limits for the last 2 years. Findings: 1. Review of chemistry analytes beta human chorionic gonadotropin, vitamin B12, Ferritin, Free T4, PSA and thyroid stimulating hormone QC showed no instrument printouts or way to access QC in computer for the last 2 years. The laboratory could not provide documentation of laboratory director reviewing QC. 2. Review of hematology complete blood count QC showed no instrument printouts or way to access QC in computer for the last 2 years. The laboratory could not provide documentation of laboratory director reviewing QC. 3. Interview with the technical supervisor on December 14, 2018 at 11:30 AM confirmed the laboratory director could not provide documentation of QC review for chemistry analytes beta human chorionic gonadotropin, vitamin B12, Ferritin, Free T4, PSA, thyroid stimulating hormone and hematology complete blood count for the last 2 years.</p>
<p>D6094</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p> <p>The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.</p>

This STANDARD is not met as evidenced by:
Based on review of chemistry and hematology quality control (QC) and interview with the technical supervisor the laboratory director failed to ensure quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. Findings: 1. Review of chemistry analytes beta human chorionic gonadotropin, vitamin B12, Ferritin, Free T4, PSA and thyroid stimulating hormone QC showed no instrument printouts or way to access QC in computer for the last 2 years. The laboratory could not provide documentation of laboratory director reviewing QC and identifying failures in quality. 2. Review of hematology complete blood count QC showed no instrument printouts or way to access QC in computer for the last 2 years. The laboratory could not provide documentation of laboratory director reviewing QC and identifying failures in quality. 3. Interview with the technical supervisor on December 14, 2018 at 11:30 AM confirmed the laboratory director could not provide documentation of QC review and identifying failures in quality for chemistry analytes beta human chorionic gonadotropin, vitamin B12, Ferritin, Free T4, PSA, thyroid stimulating hormone and hematology complete blood count for the last 2 years.

D6123

TECHNICAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1451(b)(8)(iii)

The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.

This STANDARD is not met as evidenced by:
Based on review of chemistry and hematology quality control (QC) and interview with the technical supervisor the technical supervisor failed to review QC for the last 2 years. Findings: 1. Review of chemistry analytes beta human chorionic gonadotropin, vitamin B12, Ferritin, Free T4, PSA and thyroid stimulating hormone QC showed no instrument printouts or way to access QC in computer for the last 2 years. The laboratory could not provide documentation of technical supervisor reviewing QC. 2. Review of hematology complete blood count QC showed no instrument printouts or way to access QC in computer for the last 2 years. The laboratory could not provide documentation of technical supervisor reviewing QC. 3. Interview with the technical supervisor on December 14, 2018 at 11:30 AM confirmed the technical supervisor could not provide documentation of QC review for chemistry analytes beta human chorionic gonadotropin, vitamin B12, Ferritin, Free T4, PSA, thyroid stimulating hormone and hematology complete blood count for the last 2 years.