

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 17D0452504	(X3) Date Survey Completed 08/20/2024
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
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on the review of the CMS116 test lists, proficiency testing enrollment, lack of documentation of accuracy checks from 9/29/22 to 12/31/23 and interview with technical consultant (TC) #3, the laboratory failed to verify the accuracy of wet preps and KOH testing twice a year for 9/29/22 to 12/31/23. Findings: 1. Review of the CMS116 test lists and proficiency testing enrollment for 2022 and 2023 revealed the laboratory was not enrolled in proficiency testing for wet preps and KOH testing. 2. Request was made for documentation of accuracy checks for wet preps and KOH testing from 9/29/22 to 12/31/23. No documentation for this request was made available at the time of survey. 3. Based on the CMS116 test volumes listed, approximately 435 patient results were reported from 9/29/22 to 12/31/23. 2. Interview with TC #3 on 8/20/24 at 11:50 a.m. confirmed, the laboratory failed to verify the accuracy of wet preps and KOH testing twice a year for 9/29/22 to 12/31/23.</p>
D5449	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.</p>

This STANDARD is not met as evidenced by:
Based on the review of the CMS116 test lists, quality control (QC) records and patient test records for the Amnisure Rupture of Fetal Membrane (ROM), lack of an individual quality control plan (IQCP) and interview with TC #3, the laboratory failed to perform a positive and negative control material each day of patient testing on Amnisure ROM test system. Findings: 1. Review of the CMS116 test list revealed Amnisure ROM testing was performed. This is listed by the FDA as a moderate complexity assay. 2. The surveyor requested QC and patient records for review. Review of these records revealed QC was not performed each day of patient testing. Both QC and patient results are reported as positive or negative. 3. Surveyor asked how often external QC was performed. TC #3 stated the Positive and Negative QC was performed monthly. Testing was discontinued 5/16/24. No IQCP was made available at the time of survey for the reduced QC interval. 4. Review of patient test reports revealed 10 patient results were reported from 11/8/22 to 5/8/24 without external QC testing. 6. Interview with the TC#3 on 8/20/24 at 11:05a.m. confirmed, the laboratory failed to perform a positive and negative control material each day of patient testing on Amnisure ROM test system.

D5775

COMPARISON OF TEST RESULTS

CFR(s): 493.1281(a)(c)

(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.

This STANDARD is not met as evidenced by:
Based on the review of the CMS-116 test lists, lack of comparison study documents, and interview with TC #3, the laboratory failed to perform comparison studies on automated white blood cell differentials (WBC Diff) and manual WBC Diff for 2023 and to date of survey 2024. Findings: 1. Review of the CMS116 test lists revealed that WBC diff is performed by both an automated method on the Sysmex XN-330 analyzer and by a visual manual count performed using a microscope. 2. The surveyor requested documentation of twice a year comparisons of the two methodologies for 2023 and to date of survey 2024. No documentation of a twice yearly comparison studies was provided at the time of survey. 3. Approximately 1,850 manual WBC diff patient results were reported from 1/1/23 to date of survey. 4. Interview with TC#3 on 8/20/24 at 12:05 p.m. confirmed, the laboratory failed to perform comparison studies on automated WBC Diff and manual WBC Diff for 2023 and to date of survey 2024.