| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 04D1062383 | 08/06/2025 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Northwest Medical Plaza At Sugar Creek | 1102 Nw Lowes Ave Suite 2, Bentonville, AR | |

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 |
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| **D2009** | TESTING OF PROFICIENCY TESTING SAMPLES<br>CFR(s): 493.801(b)(1)<br><br>(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.<br><br>This STANDARD is not met as evidenced by:<br>Based upon a review of the American Proficiency Testing Institute (API) proficiency test attestation records for ten events in 2024 and 2025, lack of documentation, and interviews with laboratory staff, it was determined that required signatures to attest to the routine integration of proficiency test samples in the patient workload were not present on 3 of the ten events reviewed. Survey findings follow: A) Review of the attestation forms for API Microbiology 2024 3rd proficiency test event for tissue KOH examinations revealed that it was not signed by the testing personnel. B) Review of the attestation forms for API Microbiology 1st event 2024 and API Hematology/Coagulation 2nd event 2024 revealed they were not signed by the laboratory director or designee. C) In an interview, at 11:15 a.m.on 8/6/25, the laboratory staff member (# 1 as listed on the form CMS-209) confirmed the API proficiency testing attestation forms identified above were not signed by the required personnel. |
| **D6032** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(14)<br><br>(e)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required |

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| | prior to reporting patient test results.<br><br>This STANDARD is not met as evidenced by:<br>. Based upon review of personnel files for two testing personnel listed on the form CMS-209, lack of documentation, and interviews with laboratory staff, the laboratory director failed to authorize two of two testing personnel to perform testing without direct supervision. Survey findings include: A) Review of personnel files for two testing personnel listed on form CMS-209 (Personnel #'s 1, 2 ) revealed written authorization from the laboratory director to perform moderately complex testing without direct supervision was not present. B) In an interview, at 11:15 a.m. on 8/6 /25, laboratory staff member #1 (as listed on the form CMS-209) confirmed the lack of written authorizations to test for employees (#'s 1,2 on form CMS 209). |
| **D6046** | TECHNICAL CONSULTANT RESPONSIBILITIES<br>CFR(s): 493.1413(b)(8)<br><br>(b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. The procedures for evaluation of the competency of the staff must include, but are not limited to--<br><br>This STANDARD is not met as evidenced by:<br>Based upon review of the testing personnel records, a review of the procedure manual, and interviews with laboratory staff, the technical consultant failed to evaluate the competency of testing personnel for 2024 and 2025 using the six required methods for evaluating testing personnel competency. Findings follow: A) In review of the procedure manual there were no policies addressing the evaluation of testing personnel with the following components as required by the CLIA regulations: a. Assessment of problem solving skills b. Direct observation of routine patient test performance, including patient preparation. c. Monitoring the recording and reporting of test results. d. Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records e. Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. B) In review of personnel records for testing personnel ( #2 on the form CMS 209) , it was determined the competency assessments documented in 2023 and 2024 did not address the following components required for evaluation of personnel at least annually as outlined in the CLIA regulations: a. Assessment of problem solving skills b. Direct observation of routine patient test performance, including patient preparation c. Monitoring the recording and reporting of test results. d. Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records e. Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. C) In an interview at 10:58 on 8/6/25 employee #1 (as listed on the form CMS-209) confirmed the laboratory has no policy for, or any documentation of, performing competency assessment using: assessment of problem solving skills; direct observation; monitoring recording and reporting of test results; review of worksheets; quality control records; maintenance; and proficiency samples; or assessment through blind testing samples. |