| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 01D0902798 | 01/28/2026 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Panacea O'Neill Medical Group | 104 Spenryn Dr, Madison, AL | |

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 on a review of the Wisconsin State Laboratory of Hygiene (WSLH) Proficiency Testing (PT) records and an interview with the Laboratory Director (LD), the LD and testing analysts (TA) failed to sign the PT attestation statements for the specialty in Hematology. This was noted for two of three events in 2024 and three of three events reviewed in 2025. The findings include: 1. A review of the WSLH PT records revealed no signature by the LD (or designee) and TA on attestation statements for the following surveys: a) No LD or TA signature on 2025 Hematology 1st through 3rd Events. b) No TA signature on 2024 Hematology 2nd and 3rd Events. 2. During the exit interview on 1/28/2026, at 2:10 PM, the LD confirmed the above findings. |
| **D5221** | EVALUATION OF PROFICIENCY TESTING PERFORMANCE<br>CFR(s): 493.1236(d)<br><br>All proficiency testing evaluation and verification activities must be documented.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of the 2024-2025 Wisconsin State Laboratory of Hygiene (WSLH) Proficiency Testing (PT) records and an interview with the Laboratory Director (LD), the LD failed to document review of returned PT results. This was noted for four of six PT events reviewed from 2024 to 2025. The findings are: 1. A review of the WSLH Hematology PT records revealed no documentation of review by the LD for |

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| | the following surveys: A.) Event #3-2024. B.) Event #1-3 2025. 2. During the exit interview on 1/26/2026 at 2:10 PM, the LD confirmed the above results. |
| **D5437** | CALIBRATION AND CALIBRATION VERIFICATION<br>CFR(s): 493.1255(a)<br><br>(a )Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (a)(1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (a)(2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (a)(2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (a)(2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (a)(3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of the Hematology calibration records and an interview with the Laboratory Director (LD), the Laboratory failed to perform calibrations on the Beckman Coulter DxH 520 Hematology analyzer every six months. The laboratory failed to perform one of two calibrations due second half of 2025. This is a repeat deficiency. The findings include: 1. A review of the Hematology calibration records revealed the DxH 520 was calibrated 1/31/2025 and then 11 months later on 1/5/2026. There was documentation of a calibration performed 7/21/2025 with no evidence if it passed. 2. During the exit interview on 1/28/2026, at 2:10 PM, the LD confirmed the above findings. |
| **D6000** | MODERATE COMPLEXITY LABORATORY DIRECTOR<br>CFR(s): 493.1403<br><br>The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.<br><br>This CONDITION is not met as evidenced by:<br>Based on reviews of the Proficiency Test (PT) records, DxH 520 calibration records, DxH 520 validation records, lack of Technical Consultant, Personnel records, and interviews with the Laboratory Director (LD), the LD: 1) failed to sign the PT attestation statements for the specialty in Hematology; 2) failed to document review of returned proficiency test results; 3) failed to perform calibrations on the Beckman Coulter DxH 520 Hematology analyzer every six months; 4) failed to document review and approval of the DxH 520 validation procedures prior to instrument use for patient testing on 7/31/2024; 5) failed to fill the Technical Consultant (TC) position after the previous Technical Consultant was terminated; and 6) failed to evaluate semi-annual competencies for Testing Personnel (TP) performing moderate complexity testing. The findings include: 1. Refer to D2009. 2. Refer to 5221. 3. Refer to D5437. 4. Refer to D6013. 5. Refer to D6036 6. Refer to D6053. |
| **D6013** | LABORATORY DIRECTOR RESPONSIBILITIES |

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| | CFR(s): 493.1407(e)(3)(ii)<br><br>(e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of the validation records for the Beckman Coulter DxH 520 Hematology analyzer and an interview with the Laboratory Director (LD), the LD failed to document review and approval of the validation procedures prior to instrument use for patient testing on 7/31/2024. This was noted for one of one new analyzer since previous survey on 2/13/2024 The findings include: 1. A review of Beckman Coulter DxH 520 validation records revealed no evidence of the Laboratory Director's review and approval (as evidenced by signature and date) before the instrument was utilized for patient testing on 7/31/2024. 2. During the exit interview on 1/28/2024 at 2:10 PM, the LD confirmed the above findings. |
| **D6033** | TECHNICAL CONSULTANT-MODERATE COMPLEXITY<br>CFR(s): 493.1409<br><br>The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.<br><br>This CONDITION is not met as evidenced by:<br>Based on a review of laboratory records and interviews with the Laboratory Director, the LD failed to fill the Technical Consultant position after the previous TC was terminated. Failures were noted to occur from the date the TC was terminated in July 2024 to the date of the current survey on 1/28/2026. The findings include: 1. Refer to D6036. |
| **D6036** | TECHNICAL CONSULTANT RESPONSIBILITIES<br>CFR(s): 493.1413<br><br>The technical consultant is responsible for the technical and scientific oversight of the laboratory. The technical consultant is not required to be onsite at all times testing is performed; however, he or she must be available to the laboratory on an as needed basis to provide consultation, as specified in paragraph (a) of this section.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of the CMS 209 form (Laboratory Personnel Report) and an interview with the Laboratory Director (LD), the LD failed to fill the Technical Consultant (TC) position after the previous Technical Consultant was terminated. This was noted from July 2024 to the date of the current survey on 1/28/2026. The findings include: 1. A review of the 209 Laboratory Personnel Report revealed no qualified personnel documented as Technical Consultant 2. During the exit interview on 1/28 /2026 at 2:10 PM, the LD confirmed the TC was terminated and he was not aware of the required TC qualifications. |
| **D6053** | TECHNICAL CONSULTANT RESPONSIBILITIES<br>CFR(s): 493.1413(b)(9) |

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| | (b)(9) Evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of the personnel records and an interview with the Laboratory Director (LD), the LD failed to evaluate semi-annual competencies for Testing Personnel (TP) performing moderate complexity testing. This was noted for two of three testing personnel listed on the CMS-209 (Laboratory Personnel Report) in 2024. The findings include: 1. A review of the personnel records revealed no evidence of evaluation by the LD for the semi-annual competencies of TP #2 and 3 in 2024 listed on the CMS-209. 2. During the exit interview on 1/28/2026, at 2:10 PM, the LD confirmed the above findings. |