

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D0902798	(X3) Date Survey Completed 04/14/2025
Name of Provider or Supplier Panacea O'Neill Medical Group	Street Address, City, State 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
D0000	The following deficiencies are a result of a desk review of proficiency testing scores obtained from the national database and verified with the laboratory's proficiency testing provider, WSLH (Wisconsin State Laboratory of Hygiene) Proficiency Testing. The laboratory was found to be out of compliance with CONDITION LEVEL DEFICIENCIES, as follows: D2016 - 42 C.F.R. 493.803 Condition: Successful participation [proficiency testing] D6000 - 42 C.F.R. 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director .
D2016	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.</p> <p>This CONDITION is not met as evidenced by: Based on off-site proficiency testing (PT) desk reviews of the CASPER Reports</p>

0153D and 0155D (Individual Laboratory Profiles from the Centers of Medicare and Medicaid Services [CMS]), and PT evaluation reports from WSLH (Wisconsin State Laboratory of Hygiene) Proficiency Testing, the laboratory failed to successfully participate (achieve scores of 80% or greater) in proficiency testing for White Blood Cells (WBC), WBC Differential, Hemoglobin, and the Specialty of Hematology. The laboratory failed two consecutive PT events in 2024-2025, resulting in initial unsuccessful proficiency testing performance. Refer to D2130 and D2131. .

D2130

HEMATOLOGY
CFR(s): 493.851(f)

(f) Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:
Based on off-site proficiency testing (PT) desk reviews of the CASPER Reports 0153D and 0155D (Individual Laboratory Profiles from the Centers of Medicare and Medicaid Services [CMS]), an interview with the Laboratory Director, and an email with PT evaluation reports from WSLH (Wisconsin State Laboratory of Hygiene) Proficiency Testing, the laboratory failed to successfully participate (achieve scores of 80% or greater) in proficiency testing for White Blood Cells (WBC), WBC Differential, and Hemoglobin in two consecutive 2024-2025 events, resulting in initial unsuccessful performance. The findings included: 1. Based on review of the CASPER Report 0153D and 0155D Individual Laboratory Profile reports, the laboratory received failing scores in two consecutive events, resulting in initial unsuccessful PT performance, as follows: A. 2024-Event #3: 40% for White Blood Cells; 0% for the WBC Differential; and 0% for Hemoglobin B. 2025-Event #1: 20% for White Blood Cells; 0% for the WBC Differential; and 0% for Hemoglobin 2. In a telephone interview on 4/14/2025 at 10:35 AM, the Laboratory Director confirmed the failing scores, stating the laboratory had a new Hematology analyzer, a Beckman Coulter DxH520. The laboratory had failed to order compatible PT for the new instrument for Event #3, 2024, and failed to specify the correct PT module in the 2025 re-enrollment order with WSLH. 3. In a 4/14/2024 email, the WSLH representative provided the laboratory's PT results, confirming the above scores. In addition, the representative stated WLSH provided instructions on ordering the correct PT module, but the laboratory "never followed through with letting us know of the needed program change at re-enrollment time ...". .

D2131

HEMATOLOGY
CFR(s): 493.851(g)

(g) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:
Based on off-site proficiency testing (PT) desk reviews of the CASPER Reports 0153D and 0155D (Individual Laboratory Profiles from the Centers of Medicare and Medicaid Services [CMS]), an interview with the Laboratory Director, and an email with PT evaluation reports from WSLH (Wisconsin State Laboratory of Hygiene) Proficiency Testing, the laboratory failed to successfully participate (achieve scores of

80% or greater) in proficiency testing for the specialty of Hematology in two consecutive 2024-2025 events, resulting in initial unsuccessful performance. The findings included: 1. Based on review of the CASPER Report 0153D and 0155D Individual Laboratory Profile reports, the laboratory received failing scores in two consecutive events, resulting in initial unsuccessful PT performance, as follows: A. 2024-Event #3-Hematology: 50% B. 2025-Event #1-Hematology: 50% 2. In a telephone interview on 4/14/2025 at 10:35 AM, the Laboratory Director confirmed the failing scores, stating the laboratory had a new Hematology analyzer, a Beckman Coulter DxH520. The laboratory had failed to order compatible PT for the new instrument for Event #3, 2024, and failed to specify the correct PT module in the 2025 re-enrollment order. 3. In a 4/14/2024 email, the WSLH representative provided the laboratory's PT results, confirming the above scores. In addition, the representative stated WLSH provided instructions on ordering the correct PT module, but the laboratory "never followed through with letting us know of the needed program change at re-enrollment time...". .

D6000

MODERATE COMPLEXITY LABORATORY DIRECTOR
CFR(s): 493.1403

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.

This CONDITION is not met as evidenced by:
Based on off-site proficiency testing (PT) desk reviews of the CASPER Reports 0153D and 0155D (Individual Laboratory Profiles from the Centers of Medicare and Medicaid Services [CMS]), an interview with the Laboratory Director, and an email with proficiency testing evaluation reports from WSLH (Wisconsin State Laboratory of Hygiene) Proficiency Testing, the laboratory director failed to ensure successful participation in an HHS approved proficiency testing program. Refer to D6016. .

D6016

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(4)(i)

(e)(4)(i) The proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:
Based on off-site proficiency testing (PT) desk reviews of the CASPER Reports 0153D and 0155D (Individual Laboratory Profiles from the Centers of Medicare and Medicaid Services [CMS]), an interview with the Laboratory Director, and an email with PT evaluation reports from WSLH (Wisconsin State Laboratory of Hygiene) Proficiency Testing, the laboratory director failed to ensure the laboratory had successful participation in an HHS approved proficiency testing program for White Blood Cells (WBC), WBC Differential, Hemoglobin, and the Specialty of Hematology for two consecutive 2024 - 2025 WSLH PT events, resulting in initial unsuccessful participation. Refer to D2130 and D2131.