

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D0902798	(X3) Date Survey Completed 05/21/2021
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
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 a review of the CMS (Centers for Medicare and Medicaid) CASPER reports and a review of API (American Proficiency Institute) proficiency testing evaluations, the surveyor determined the laboratory failed to successfully participate in proficiency testing for Hematocrit (HCT) for two consecutive testing events. These failures resulted in an initial unsuccessful participation. This affected Event #3, 2020 and Event #1, 2021. The findings include: 1. A review of the CASPER reports revealed the laboratory scored forty percent (40 %) for HCT for Event #3, 2020, and 60 % for</p>

Event #1, 2021. These two consecutive failures of the same analyte resulted in an initial unsuccessful participation in proficiency testing. 2. A review of the API testing evaluations confirmed the above noted findings.

D2130

HEMATOLOGY
CFR(s): 493.851(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 a review of the CMS CASPER reports and a review of API (American Proficiency Institute) proficiency testing evaluations, the surveyor determined the laboratory failed to satisfactorily perform in proficiency testing for Hematocrit (HCT) for two consecutive testing events. These failures resulted in an initial unsuccessful participation. This affected Event #3, 2020 and Event #1, 2021. The findings include: 1. A review of the CASPER reports revealed the laboratory scored forty percent (40 %) for HCT for Event #3, 2020, and 60 % for Event #1, 2021. These two consecutive failures of the same analyte resulted in an initial unsuccessful participation in proficiency testing. 2. A review of the API testing evaluations confirmed the above noted findings.