Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D0902798	(X3) Date Survey Completed 02/04/2022
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	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (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. This CONDITION is not met as evidenced by: Based on a review of the CMS (Centers for Medicare and Medicaid) CASPER Reports for Proficiency Testing (PT), API (American Proficiency Institute) PT evaluations, and telephone interview with testing personnel, the surveyor determined the laboratory failed to successfully participate in Hematocrit (HCT) for three out of four consecutive events Event #3 2020, Event #1 2021, and Event #3 2021. The failures of HCT for these three out of four consecutive events resulted in a non-initial unsuccessful participation. The findings include: 1. Refer to D2123. 2. Refer to D2130.

D2123	HEMATOLOGY CFR(s): 493.851(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by: Based on a review of the CMS (Centers for Medicare and Medicaid Services) Casper reports, a review of the API (American Proficiency Institute) proficiency testing records, and a telephone interview with testing personnel, the surveyor determined the laboratory failed to participate in Hematocrit (HCT) testing for Events #3 2021. This failure along with D2130 resulted in a non-initial unsuccessful participation for the laboratory. The finding include: 1. A review of the CASPER reports revealed the laboratory failed to participate in 2021 Event #3 resulting in a score of zero for HCT. 2. A review of the API proficiency testing confirmed the above noted findings. 3. During a telephone interview on 02/04/2022 at 10:00 AM, the testing personnel explained when the samples came in for Event #3 2021 she was the only testing personnel trained to perform Proficiency Testing (PT), and was out of the office, due to being sick. New Testing Personnel was performing patient testing for for Complete Blood Count (CBC which included the HCT) during this time.
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 (Centers for Medicare and Medicaid Services) Casper reports, a review of the API (American Proficiency Institute) proficiency testing records, and a telephone interview with testing personnel, the surveyor determined the laboratory failed to satisfactorily perform in proficiency testing for Hematocrit (HCT) testing for three out of four consecutive testing events. These failures resulted in a non-initial unsuccessful participation for the laboratory The finding include: 1. A review of the CASPER reports revealed the laboratory scored forty percent (40 %) for HCT for Event #3 2020 and sixty percent (60 %) for Event #1 2021. For 2021 Event #3 the laboratory failed to participate resulting a score of zero for HCT. 2. A review of the API proficiency testing confirmed the above noted findings. 3. During a telephone interview on 02/04/2022 at 10:00 AM, the testing personnel explained when the samples came in for Event #3 2021 she was the only testing personnel trained to perform Proficiency Testing (PT), and was out of the office, due to being sick. New Testing Personnel was performing patient testing for for Complete Blood Count (CBC which included the HCT) during this 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 the CMS (Centers for Medicare and Medicaid) CASPER reports and a review of the American Proficiency Institute (API) proficiency testing reports, the surveyor determined the Laboratory Director failed to fulfill the Laboratory Director's responsibilities. The failures of Hematocrit (HCT) for these three out of four consecutive events resulted in a non-initial unsuccessful participation. The findings include: 1. Refer to D6016.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on the CMS (Centers for Medicare and Medicaid) CASPER reports and a review of the American Proficiency Institute (API) proficiency testing reports, the surveyor determined the Laboratory Director failed to ensure proficiency testing samples are tested as required. This affected Hematology [Complete Blood Count (CBC) which include Hematocrit] testing for Event #3 2021. The findings inlcude: 1. Refer to D2123. 2. Refer to D2130.