

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D0902798	(X3) Date Survey Completed 03/08/2022
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
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on a review of API (American Proficiency Institute) proficiency testing (PT) records and an interview with Testing Personnel #1, the surveyor determined the laboratory failed to ensure proficiency testing samples were rotated between all personnel who performed patient testing. This was noted on six out of seven Hematology surveys reviewed for 2019 (3rd Event), 2020 (all three events), and 2021 (all three events). The findings include: 1. A review of API attestation statements revealed Testing Personnel #1 had performed all the testing on six out of seven Hematology surveys reviewed. 2. During an interview on 03/08/2022 at 11:45 AM, Testing Personnel #1 confirmed the proficiency testing was not rotated with Testing Personnel #2 because she was not comfortable with her running the PT samples. The surveyor asked if Testing Personnel #2 performed patient testing; Testing Personnel #1 confirmed has performed patient testing since August 2020.</p>
D6033	<p>TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409</p> <p>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.</p> <p>This CONDITION is not met as evidenced by:</p>

Based on a review of the Laboratory Personnel Report (CLIA CMS - 209), personnel records, and an interview with the Laboratory Director, the laboratory failed to have a qualified individual to fulfill the position as Technical Consultant. This was noted from July 2021 to the survey date (03/08/2022). The findings include: 1. Refer to D6035.

D6035

TECHNICAL CONSULTANT QUALIFICATIONS
CFR(s): 493.1411

(a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service.

This STANDARD is not met as evidenced by:

Based on a review of the Laboratory Personnel Report (CLIA CMS - 209), personnel records, and an interview with the Laboratory Director, the laboratory failed to have a qualified individual to fulfill the position as the Technical Consultant. This was noted from July 2021 to the survey date (03/08/2022). The findings include: 1. A review of the Laboratory Personnel Report (CLIA CMS - 209) revealed the Laboratory Director intended to fulfill the position as the Technical Consultant. 2. A review of the personnel records revealed the Laboratory Director could not provide documentation of at least one year of laboratory training or experience in non-waived testing for

Hematology, and thus failed to meet the CLIA requirements to qualify as the Technical Consultant. 3. During an interview on 03/08/2022 at 10:35 AM, the Laboratory Director confirmed the above findings.