Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0902798	02/13/2024
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
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) 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 This STANDARD is not met as evidenced by: Based on a review of the Laboratory Personnel Report (CMS-209), a review of API (American Proficiency Institute) and Wisconsin State Laboratory of Hygiene (WSLH) proficiency testing (PT) records and an interview with Testing Personnel #1, the laboratory failed to ensure proficiency testing samples were rotated between all personnel who performed patient testing. This was noted for two testing personnel on five out of six Hematology proficiency testing events reviewed for 2022 and 2023. This is a repeat deficiency. The findings include: 1. A review of the laboratory's current Laboratory Personnel Report revealed two Testing Personnel that should be participating in and rotating proficiency testing samples. 2. A review of API and WSLH attestation statements revealed: a. Testing Personnel #1 performed 2022 Events 1-3 and 2023 Events 1 and 2. b. Testing Personnel #2 performed 2023 3rd Event. 3. During an interview on 2/13/2024 at 11:44 AM, Testing Personnel #1 confirmed the above findings.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)

	(3)-- (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 (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on a review of the Hematology calibration records, Horiba ABX Micros 60 hematology analyzer user manual, and an interview with Testing Personnel #1, the Laboratory failed to perform calibration on the Horiba ABX Micros 60 analyzer every six months as per the manufacturers recommendation. This was noted for one of four calibrations reviewed from 2022 to 2024. The laboratory failed to perform one calibration due January 2024. The findings include: 1. A review of the Hematology calibration records revealed the Micros 60 was calibrated on 7/7/2022, 1/16/2023, and 7/18/2023. There was no documentation of a calibration performed January 2024. 2. A further review of the Micros 60 user manual revealed on the resource page, "The manufacturer recommends calibrating the device every 6 months." 3. During an interview on 2/13/2024, at 11:53 AM, Testing Personnel #1 confirmed the calibration due January 2024 was not performed.