Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0902798	09/03/2019
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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on a review of the 2017 - 2019 API (American Proficiency Institute) proficiency testing records and an interview with Testing Personnel (TP) #2, the laboratory failed to ensure attestation statements for four out of seven surveys were signed by the Laboratory Director and the testing personnel. The findings include: 1. A review of the API Proficiency Testing (PT) records revealed missing signatures of the Laboratory Director or the Testing Personnel on the attestation statements for the following Hematology surveys: A) 2017-Event #3, 2018-Event #1 and 2019-Event #2: No signature by the Laboratory Director B) 2018-Events #1 and #3: No signatures by the Testing Personnel (The names of the Laboratory Director, TP #1 and a previous TP had been written in the "Testing Analyst" section (not signed by the actual personnel). 2. In an interview on 9/3/2019 at 3:10 PM, the surveyor reviewed the API directions on the attestation statement which specified the Laboratory Director and Testing Analysts must physically sign the document. TP #2 confirmed TP #1 had written in the names on the attestation statements for the 2018-Events #1 and #3 surveys. TP #2 further confirmed the Laboratory Director had failed to sign three of the attestation statements. 3. In addition the above noted findings were reviewed with the Practice Manager on 9/3/2019 at 3:25 PM. .
D2010	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2) The laboratory must test samples the same number of times that it routinely tests

	patient samples. This STANDARD is not met as evidenced by: Based on a review of the API (American Proficiency Institute) proficiency testing records and an interview with Testing Personnel (TP) #2, the laboratory failed to ensure proficiency testing samples were tested the same number of times as patient samples. This was noted on one of seven surveys reviewed. The findings include: 1. A review of the 2018 Event #3 API proficiency testing records revealed three CBC (Complete Blood Count) printouts for each API PT Hematology sample (11-15), for a total of 15 printouts for the survey, all run on 11/13/2018. The surveyor noted at least two of the samples were relatively normal, and there were no error codes indicating sample problems. 2. In an interview on 9/3/2019 at 3:10 PM, the surveyor reviewed the 2018 Event #3 API proficiency testing records with TP #2 who confirmed patient CBC samples are not routinely run three times each unless there is a problem. TP #1 was unable to explain why testing personnel ran the PT sample from this survey multiple times. Thus the above noted findings were confirmed. 3. In addition the above noted findings were reviewed with the Practice Manager on 9/3/2019 at 3:25 PM. .
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on a review of the API (American Proficiency Institute) proficiency testing (PT) records and an interview with Testing Personnel #2, the surveyor determined the laboratory failed to investigate and perform corrective action for one survey with a failing score, out of seven surveys reviewed. The findings include: 1. A review of the 2018-Event #1 API proficiency testing survey revealed a failing score of 60% for RBC's (Red Blood Cells), and scores of 80% for Hemoglobin, Hematocrit, and WBC's (White Blood Cells), resulting in an overall score of 83% for this Hematology survey. 2. A review of the corrective action for this survey revealed the note, "Our CBC's [Complete Blood Counts] have been reviewed by the Lab Director. No corrective action at this time." Also included was an additional note, "Hct-3rd vial, Hb-3rd vial, RBC-3rd vial + 1 vial". There was no documentation of an investigation to determine the cause of the failure or corrective actions to prevent recurrence. 3. In an interview with Testing Personnel #2 on 9/3/2019 at 3:10 PM, the surveyor explained the CLIA requirement of performing and documenting investigation to determine the actual causes whenever PT failures occur. This is required to determine if patient results were affected so remedial actions may be taken if warranted; investigation can include repeating the samples with results less than 100%, review of recent calibrations, maintenance and quality controls for trends and shifts. Testing Personnel #2 confirmed the laboratory had not documented any additional investigation to determine the cause of the failure for this survey. 4. In addition, the above noted findings were reviewed with the Practice Manager on 9/3/2019 at 3:25 PM. .
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 reviews of the Horiba Micros 60 calibration guide, calibration and quality control records, and an interview with Testing Personnel (TP) #2, the surveyor determined the laboratory failed to follow the manufacturer's instructions to verify calibrations by running quality controls (QC) for three out of four calibrations of the Hematology analyzer performed in 2018 - 2019 The findings include: 1. A review of calibration records for the Horiba Micros 60 revealed the instrument was calibrated on the following dates as follows: A.) 7/3/2018 at 12:54 PM B.) 1/8/2019 at 1:15 PM C.) 7/9/2019 at 10:39 AM 2. A review of the monthly cumulative QC records revealed QC was only run in the early morning on the above dates. 3. During an interview on 9/3/2019 at 4:15 PM, the surveyor asked TP #2 about the manufacturer's instruction for performing a calibration on the Hematology analyzer. A review of the directions on the publication "M60 Calibration Guide when using Lite DM" revealed as the final steps under the calibration section, "...15. Run QC as normal. ...". TP #2 stated she followed the manufacturer's calibration instructions, however TP #2 was unable to provide documentation of the QC performed after calibration performed on the above dates. Thus the above noted findings were confirmed. .
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on a review of quality assurance (QA) records and an interview with Testing Personnel #1, the surveyor determined the laboratory failed to implement effective quality assessment reviews to identify and correct problems identified in the analytical systems. The findings include: 1. A review of quality assurance documentation revealed the laboratory routinely performed monthly QA activities, however the reviews were inadequate to discover and correct problems noted in the following areas: A) Failure to ensure attestation statements for four out of seven surveys were signed by the Laboratory Director and the testing personnel and ensure proficiency testing samples were tested the same number of times as patient samples. (Refer to D2009 and D2010.) B) Failure to perform and document investigation to determine the actual cause for a failing Proficiency Testing score on 2018-Event #1, a requirement to determine if patient results were affected so remedial actions may be taken if warranted. (Refer to D5221.) C) Failure to follow the manufacturer's instructions to verify calibrations by running quality controls (QC) for three out of

	four calibrations of the Hematology analyzer performed in 2018 - 2019. (Refer to D5437.) D) Failure to ensure Testing Personnel received additional training on the acceptable number of times to perform QC and implement corrective actions when the results were still outside the expected range of acceptability after two-three attempts. (Refer to D6045.) 2. During the exit summation on 9/3/2019 at 5:10 PM, these concerns were reviewed and confirmed with the Practice Manager. .
D6045	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(7) (b) The technical consultant is responsible for-- (b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; This STANDARD is not met as evidenced by: Based on a review of Hematology Quality Control (QC) records and an interview with the Practice Manager, the surveyor determined the Technical Consultant (also the Laboratory Director) failed to ensure Testing Personnel received additional training on the acceptable number of times to perform QC and implement corrective actions when the results were outside the expected range of acceptability. The findings include: 1. A review of the QC records for the Horiba ABx Hematology analyzer revealed multiple days when the QC was outside acceptable limits on the first two or three attempts. Review of the cumulative monthly QC printout from the instrument revealed many days when the QC was run repeatedly until the values were in range, for example (list is not all inclusive): A) 12/17/2018: Low (L) QC run 9 X's (times); Normal (N) run 4 X's; High (H) run 4 X's B) 01/22/2019: N QC run 10 X's C) 01/24 /2019: L QC run 8 X's D) 01/28/2019: L QC run 14 X's E) 01/29/2019: H QC run 15 X's F) 01/31/2019: L QC run 8 X's; H QC run 22 X's E) 02/01/2019: L QC run 6 X's; N and H QC each run 9 X's F) 02/05/2019: L QC run 7 X's G) 02/20/2019: L QC run 5 X's H) 06/17/2019: N QC run 8 X's I) 06/18/2019: N QC run 11 X's; H QC run 4 X's 2. During interviews on 9/3/2019 at 3:15 with Testing Personnel #2 and at 3:25 PM with the Practice Manager, the surveyor reviewed and confirmed the above noted findings. The Practice Manager confirmed the Testing Personnel should not be running the QC an excessive number of times as was their practice when QC was outside acceptable limits. SURVEYOR ID #32558 Licensure and Certification Surveyor