Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D1025212	(X3) Date Survey Completed 10/30/2019
Name of Provider or Supplier Physicians At Sweetwater, Pllc	**Street Address, City, State** 16659 Sw Frwy, Suite 301, Building Ii, Sugar Land, TX	
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
D0000	The laboratory was found out of compliance with the CLIA regulations. The conditions not met were: D2016 - 42 C.F.R. 493.803 Condition: Successful participation [proficiency testing] D2017 - 42 C.F.R. 493.807(a) - Reinstatement After Failure D6000 - 42 C.F.R. 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director; The facility representative was given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit.
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 review of proficiency testing records and interview of facility personnel, the laboratory failed to successfully participate in a proficiency testing program for the specialty of routine hematology for the analyte Red Cell Count (RBC), Hematocrit (HCT), Hemaglobin (Hgb), White blood count (WBC), Platelet (PLT), and Cell ID. Refer to D2130, D2131
D2017	REINSTATEMENT OF NONWAIVED LABORATORIES CFR(s): 493.807(a)(b) (a) If a laboratory's certificate is suspended or limited or its Medicare or Medicaid approval is cancelled or its Medicare or Medicaid payments are suspended because it fails to participate successfully in proficiency testing for one or more specialties, subspecialties, analyte or test, or voluntarily withdraws its certification under CLIA for the failed specialty, subspecialty, or analyte, the laboratory must then demonstrate sustained satisfactory performance on two consecutive proficiency testing events, one of which may be on site, before CMS will consider it for reinstatement for certification and Medicare or Medicaid approval in that specialty, subspecialty, analyte or test. (b) The cancellation period for Medicare and Medicaid approval or period for suspension of Medicare or Medicaid payments or suspension or limitation of certification under CLIA for the failed specialty, subspecialty, or analyte or test is for a period of not less than six months from the date of cancellation, limitation or suspension of the CLIA certificate. This CONDITION is not met as evidenced by: Based on review of Centers for Medicare and Medicaid Services (CMS) form 0155 and American Board of Bioanalysts (AAB) proficiency testing records, it was determined the laboratory had not successfully participated in proficiency testing for the satisfactory performance in the specialty of hematology for the analytes: analyte Red Cell Count (RBC), Hematocrit (HCT), Hemaglobin (Hgb), White blood count (WBC), Platelet (PLT), and Cell ID resulting in a non-initial PT failure. Findings were: RBC 1. Review of AAB PT records for 2018 for red blood cells revealed the laboratory received the following scores for the 2018 Hematology 1st event and 3rd event, and 2019 2nd and 3rd events: AAB 1st event 2018 = 40% AAB 3rd event 2018 = 0% (not reported) AAB 2nd event 2019 = 0% (not reported) AAB 3rd event 2019 = 0% (not reported) Hematocrit 2. Review of PT records for 2018 for hematocrit revealed the laboratory received the following scores for the 2018 Hematology 1st event and 3rd event, and 2019 2nd and 3rd events: AAB 1st event 2018 = 20% AAB 3rd event 2018 = 0% (not reported) AAB 2nd event 2019 = 0% (not reported) AAB 3rd event 2019 = 0% (not reported) Red Cell Count (RBC), Hematocrit (HCT), Hemaglobin (Hgb), White blood count (WBC), Platelet (PLT), and Cell ID 3. Review of PT records for 2019 revealed the laboratory received the following scores for the 2019 2nd and 3rd events. AAB 2nd event 2019 = 0% (not reported) AAB 3rd event 2019 = 0% (not reported) 4. The laboratory must demonstrate sustained satisfactory performance (>/= 80%) on two consecutive testing events for reinstatement. 5. An interview with the primary testing person on 10/30/19 at 1040 hours in the laboratory confirmed the above findings.
D2121	HEMATOLOGY CFR(s): 493.851(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.

	This STANDARD is not met as evidenced by: Based on review of the 2018 and 2019 American Board of Bioanalysts (AAB) proficiency testing (PT) records and confirmed in interview, the laboratory failed to obtain at least 80% for the hematology analyte Red Cell Count (RBC), Hematocrit (HCT), Hemaglobin (Hgb), White blood count (WBC), Platelet (PLT), and Cell ID. Findings were: 1. Review of AAB PT records for 2018 for red blood cells revealed the laboratory received the following scores for the 2018 Hematology 1st event and 3rd event: AAB 1st event 2018 = 40% sample lab result (x10E12/L) Hem-01 6.06 (acceptable result 5.16 - 5.82) Hem-03 2.49 (acceptable result 2.19 - 2.47) Hem-04 5.96 (acceptable result 5.14 - 5.79) AAB 3rd event 2018 = 0% (not reported) 2. Review of PT records for 2018 for hematocrit revealed the laboratory received the following scores for the 2018 Hematology 1st event and 3rd event: AAB 1st event 2018 = 20% sample lab result (%) acceptable result Hem-1 59.3 49.3 - 55.6 Hem-2 41.7 36.8 - 41.5 Hem-3 19.4 16.8 - 18.9 Hem-4 57.8 48.9 - 55.2 AAB 3rd event 2018 = 0% (not reported) 3. Review of PT records for 2018 for hemoglobin, WBC and platelets revealed the laboratory received the following scores for the 2018 3rd event. AAB 3rd event 2018 = 0% (not reported) 4. Review of PT records for 2019 for Cell ID revealed the laboratory received the following scores for the 2019 1st event. AAB 1st event 2019 = 0% (not reported) 5. Review of PT records for 2019 for the analytes Red Cell Count (RBC), Hematocrit (HCT), Hemaglobin (Hgb), White blood count (WBC), Platelet (PLT), and Cell ID received the following scores for the following events. AAB 2nd event = 0% (not reported) AAB 3rd event = 0% (not reported) 6. An interview with the primary testing person on 10/30/19 at 1040 hours in the laboratory confirmed the above findings. She stated that another testing person who no longer worked with them was responsible for the PT.
D2122	HEMATOLOGY CFR(s): 493.851(b) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance. This STANDARD is not met as evidenced by: Based on a review of the laboratory American Board of Bioanalysts (AAB) proficiency testing records from 2018-2019 and interview of facility personnel, the laboratory failed to attain an overall testing event score of at least 80 % for each event which constitutes unsatisfactory performance. Findings were: 1. A review of 4 of 6 AAB proficiency testing revealed a hematology event score of less than 80% (unsatisfactory performance) for the following testing events: 2018 AAB 1st event Hematology: 76% 2018 AAB 3rd event Hematology: 13% 2019 AAB 2nd event Hematology: 0% 2019 AAB 3rd event Hematology: 0% 2. An interview with the primary testing person on 10/30/19 at 1000 hours in the laboratory confirmed the above findings. She stated that another testing person who no longer worked with them was responsible for the PT.
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 2018 - 2019 American Board of Bioanalysts (AAB) proficiency testing (PT) records and interview of facility personnel it was revealed that the laboratory failed to participate in the 2nd and 3rd hematology testing events of 2019 and 3rd hematology event of 2018. Findings were: 1. A review of the CMS national proficiency testing database revealed a score of "0" on the 2nd and 3rd hematology event of 2019 for this facility. 2. A review of AAB PT records revealed the laboratory received a 0% for the 2019-2nd event and 2019-3rd event Hematology PT for "Failure to Participate." The PT summary was rated by the provider as unsatisfactory performance for all analytes for testing events 2019-2 and 2019-3 Hematology. 3. An interview of the primary testing person on 10/30/19 at 1005 hours in the laboratory confirmed the above findings. She confirmed the laboratory had discontinued CBC (complete blood count) testing in May 2019. key: CMS - Center for Medicare and Medicaid services
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 review of American Board of Bioanalysts (AAB) proficiency testing (PT) records from 2018 and 2019, and confirmed in interview, the laboratory failed to attain a satisfactory performance (score of at least 80 %) for 4 of 6 events in 2018 and 2019. Findings were: 1. Review of the 2018 AAB proficiency testing records revealed 2 of 3 consecutive events when the laboratory failed to attain at least an 80% score for the following analytes. AAB 1st event 2018 = RBC (red blood cells) 40% sample lab result (x10E12/L) Hem-01 6.06 (acceptable result 5.16 - 5.82) Hem-03 2.49 (acceptable result 2.19 - 2.47) Hem-04 5.96 (acceptable result 5.14 - 5.79) AAB 3rd event 2018 = 0% RBC (not reported) AAB 1st event 2018 = HCT (hematocrit) 20% sample lab result (%) acceptable result Hem-1 59.3 49.3 - 55.6 Hem-2 41.7 36.8 - 41.5 Hem-3 19.4 16.8 - 18.9 Hem-4 57.8 48.9 - 55.2 AAB 3rd event 2018 = 0% HCT (not reported) 2. Review of the 2019 AAB proficiency testing records revealed 2 of 3 consecutive events when the laboratory failed to attain at least an 80% score for the following analytes Red Cell Count (RBC), Hematocrit (HCT), Hemaglobin (Hgb), White blood count (WBC), Platelet (PLT), and Cell ID. AAB 2nd event 2019 - 0% (not reported) AAB 3rd event 2019 - 0% (not reported) 3. An interview with the primary testing person on 10/30/19 at 1040 hours in the laboratory confirmed the above findings. She stated that another testing person who no longer worked with them was responsible for the PT.
D2131	HEMATOLOGY

	CFR(s): 493.851(g) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on review of the CMS form 155 and American Board of Bioanalysts (AAB) proficiency testing records from 2018 - 2019 revealed that the laboratory failed to achieve satisfactory performance (80% or greater) for each event in 4 out of 6 consecutive testing events in the specialty of Hematology in 2018 and 2019. Two out of three unsatisfactory scores results in unsuccessful PT performance. Findings were: 1. Review of the AAB 2018 (event 1) revealed the laboratory received an overall score of 76% for hematology testing event. 2. Review of the AAB 2018 (event 3) revealed the laboratory received an overall score of 13% for hematology testing event. 3. Review of the AAB 2019 (2nd and 3rd events) revealed the laboratory received an overall score of 0% for hematology testing events. 4. An interview with the primary testing person on 10/30/19 at 1045 hours in the laboratory confirmed the above findings. She stated that another testing person who no longer worked with them was responsible for the PT.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on review of the 2018 and 2019 American Board of Bioanalysts (AAB) proficiency testing (PT) records and confirmed in interview, the laboratory failed to verify the accuracy of the analytes: Red Cell Count (RBC), Hematocrit (HCT), Hemaglobin (Hgb), White blood count (WBC), Platelet (PLT), and Cell ID. Findings were: 1. Review of the 2018 and 2019 AAB proficiency testing records revealed the laboratory received a "0%" with no documentation of the laboratory verifying the accuracy of the following analytes. AAB 3rd event 2018 = RBC 0% (not reported) AAB 3rd event 2018 = HCT 0% (not reported) AAB 3rd event 2018 = 0% HGB (not reported) AAB 3rd event 2018 = 0% WBC (not reported) AAB 3rd event 2018 = 0% PLT (not reported) AAB 1st event 2019 = 0% Cell ID (not reported) AAB 2nd event 2019 = 0% Red Cell Count (RBC), Hematocrit (HCT), Hemaglobin (Hgb), White blood count (WBC), Platelet (PLT), and Cell ID (not reported) AAB 3rd event 2019 = 0% Red Cell Count (RBC), Hematocrit (HCT), Hemaglobin (Hgb), White blood count (WBC), Platelet (PLT), and Cell ID (not reported) 2. An interview with the primary testing person on 10/30/19 at 1040 hours in the laboratory confirmed the above findings. She stated that another testing person who no longer worked with them was responsible for the PT.
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 review of laboratory AAB proficiency testing records and confirmed in interview, he laboratory director failed to provide overall management and direction of the laboratory services. Refer to D6016, D6019
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 review of AAB proficiency testing results and confirmed in interview, the laboratory director failed to ensure successful participation in a HHS approved proficiency testing program. Refer to D2130
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on review of laboratory's American Association of Bioanalysts (AAB) proficiency testing records and confirmed in interview, the laboratory director failed to ensure that an approved correction plan was followed when any proficiency testing were found unsatisfactory. (Refer to D2121)