Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1025212	06/20/2018
Name of Provider or Supplier	**Street Address, City, State**	
Physicians At Sweetwater, Pllc	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	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility representative(s) were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and certification is recommended. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of laboratory policy, review of manufacturer's instructions, review of patient test records, and confirmed in interview of facility personnel, the laboratory failed to follow its own policy for resolution of flagged results on CBC results. The findings were: 1. Review of the laboratory's policy titled, "Operation of the Cell-Dyn CBC Analyzer" stated the following actions for lymphocyte R0 and R2 codes: RO "Action: check specimen for clots. Review a stained smear. Verify the WBC count by an alternate method." R2 "Action: review a stained smear to confirm the results." 2. A

review of the Abbott Cell-Dyn 1800 operator's instructions (List No. 07H80-01) under the section titled "Parameter Flags" stated: "These flags are generated after the instrument evaluates the measured data for a particular parameter or group of parameters. The result may be suspect due to interfering substances or the inability of the instrument to measure a particular parameter due to a sample abnormality. The name of each flag, how it is displayed, the cause of the flag, and the action to be taken are given in the following explanations. Flag: LYM R0 or RM is displayed between the absolute and percent results of LYM. NOTE: RM means more than one alert within the same subpopulation. Cause: This flag can be caused by: -Nucleated RBCs -Platelet clumps -Giant platelets -Cryoglobulins -Incomplete lysis of RBCs -Small lymphocytes such as those found in chronic lymphocytic leukemia -Fibrin clots -Shift in WBC cell distribution due to EDTA anticoagulant equilibration Action: Check the specimen for clots or agglutination. Rerun specimen 20 minutes after collection. Follow your laboratory's review criteria or review a stained smear to confirm the differential results and verify the WBC. Redraw and rerun the specimen as required. Flag: LRI - Lower Region Interference is displayed after the PLT result. Cause: LRI is generally non-biologic and can be caused by: -Debris (dirty aperture) -Contaminated reagent -Electronic noise -Microbubbles Action: Check the Background Count. Refer to Section 5: Operating Instructions. If the Background Count exceeds the limits, troubleshoot accordingly. If the Background Count is within limits, perform another run on the same specimen. If the flag persists, review a stained smear to determine the cause of the interference and verify the PLT count by a different method. Flag: URI - Upper Region Interference is displayed after the PLT result. Cause: URI is generally due to biologic interference. The flag can be caused by: -Microcytic RBCs -Schistocytes -Giant platelets -Sickle cells -Platelet clumps NOTE: An irregular platelet histogram can indicate the presence of platelet clumps. Action: Review the MCV and the PLT histogram. If the MCV is low and/or the histogram indicates an overlap (poor separation in the upper discriminator) in the RBC and PLT populations, review a stained smear to determine the cause and confirm the PLT count. Flag: LRI URI-Multiple region interference is displayed after the PLT result. Cause: Interference is present in both the upper and lower regions of the platelet histogram. Action: Use the actions given for LRI and URI flags. Flag: LYM R1 is displayed between the absolute and percent results of LYM. Cause: This flag can be caused by: -Lymphocytosis -Lymphopenia -Cryoglobulins -Shift in WBC cell distribution due to EDTA anticoagulant equilibration. Flag: LYM R2 is displayed between the absolute and percent results of LYM. Cause: This flag can be caused by: -Lymphocytosis -Lymphopenia -Blasts -Variant lymphocytes -Plasma cells -Basophilia -Shift in WBC cell distribution due to EDTA anticoagulant equilibration. Flag: MID R2 or RM is displayed between the absolute and percent results of MID. Cause: This flag can be caused by: -Lymphocytosis -Lymphopenia -Blasts -Variant lymphocytes -Plasma cells -Basophilia -Monocytosis -Shift in WBC cell distribution due to EDTA anticoagulant equilibration. Flag: MID R3 or RM is displayed between the absolute and percent results of MID. Cause: This flag can be caused by: -Eosinophilia -Blasts -Agranular neutrophils -Plasma cells -Basophilia -Bands -Shift in WBC cell distribution due to EDTA anticoagulant equilibration. Flag: GRAN R3 or RM is displayed between the absolute and percent results of GRAN. Cause: This flag can be caused by: -Granulocytosis -Neutropenia -Eosinophilia -Agranular neutrophils -Bands -Shift in WBC cell distribution due to EDTA anticoagulant equilibration. Flag: GRAN R4 or RM is displayed between the absolute and percent results of GRAN. Cause: This flag can be caused by: -Hypersegmented neutrophils -Granulocytosis -Neutropenia -Immature granulocytes Action: For all of the above Suspect Population Flags, check the specimen for clots or agglutination. Rerun specimen 20 minutes after collection. Follow your laboratory's review criteria or review a stained smear to confirm the

	results. Redraw and rerun the specimen as required." 3. Random review of patient results from April 2018 revealed the following 2 of 3 patients that had flags on the CBC result when flag(s) were not verified by smear review or another verification method: Date: 04/13/2018 Sequence #: 5157 Flag: RO Date: 04/13/2018 Sequence #: 5158 Flag: R2 4. The above findings were confirmed in interview with testing personnel one and two (as listed on Form CMS 209) on 06/20/2018 at 1330 hours in the laboratory. Key: CBC - complete blood count WBC - white blood cell LYM - lymphocyte PLT - platelet CMS - Centers for Medicare and Medicaid Services
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of laboratory policy, review of quality control results, and confirmed in interview of facility personnel, the laboratory's quality control policy failed to determine acceptance and rejection criteria when quality control has been repeated multiple times. The findings were: 1. Review of the laboratory's policy titled, "Operation of CELL-DYN CBC Analyzer" stated under "V.Quality Control," "... Troubleshoot the Cell-Dyn 1800. -Follow the troubleshooting Guide Cell-Dyn manual -Contact the lab supervisor to troubleshoot. -Contact Cell-Dyn service." 2. Review of quality control records from January 3, 2018 through June 20, 2018 (the date of the survey) revealed the following days when quality control was repeated multiple times: Date: 3/29/2018 Lot #L8015 Run 1: 0856 hours Run 2: 0903 hours Run 3: 0936 hours Run 4: 0944 hours Run 5: 1028 hours Run 6: 1047 hours Run 7: 1104 hours Run 8: 1156 hours Run 9: 1357 hours Run 10: 1401 hours Date: 04/17/2018 April 17, 2018 Lot #N8015 Run 1: 0927 hours Run 2: 0931 hours Run 3: 0938 hours Run 4: 0951 hours Run 5: 0952 hours Run 6: 1013 hours Run 7: 1016 hours April 17, 2018 Lot #H8015 Run 1: 0929 hours Run 2: 0936 hours Run 3: 0949 hours Run 4: 1000 hours 3. The above findings were confirmed in interview of testing personnel two (as listed on Form CMS-209) on 06/20/2018 at 1230 hours in the laboratory. She confirmed that the instrument no longer had a contract and she would try multiple troubleshooting procedures on the analyzer. The troubleshooting procedure was not listed in the policy.

D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of laboratory policy, review of quality control records, and confirmed in interview of facility personnel, the laboratory's quality assurance plan failed to identify and correct errors in its analytic systems. The findings were: 1. The laboratory's quality assurance plan failed to identify that the laboratory failed to follow its own policy for resolution of flags on CBC results for random review of patient reports from April 2018 (refer to D5401). 2. The laboratory's quality assurance plan failed to identify that the laboratory's policy for performance of quality control on the CELL-DYN 1800 hematology analyzer did not instruct the testing person on what procedures to follow when quality control has been repeated multiple times (refer to D5403).