Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2058359	01/15/2019
Name of Provider or Supplier	**Street Address, City, State**	
Stuart Oncology Associates Pa	451 Sw Bethany Dr Ste 100, Port Saint Lucie, FL	

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
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 record review and interview, the laboratory failed to receive a passing proficiency test (PT) score for the third testing event of 2017 for the specialty of Hematology. Findings: Review of the PT Performance Summary from American Proficiency Institute (API) for the third event of 2017 showed unsatisfactory scores for the CMS (Center for Medicare and Medicaid Services) reportable analytes of Erythrocyte Count (40%), hematocrit (60%), and White Blood Cell Differential (60%). The overall score for the specialty of hematology was 73% (erythrocyte count 40% + hematocrit 60% + hemoglobin 80% + Leukocyte Count 100% + Platelet Count 100% + White Blood Cell Differential 60% = 440% divided by 6 analytes = 73%). During an interview on 1/15/19 at 1:50 PM, Clinical Consultant B confirmed the laboratory had failed proficiency testing.
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to run quality control

	samples on the Abbott Diagnostic Cell Dyn 1800 hematology analyzer for ten days where patients specimens were analyzed during the time period between 1/20/17 through 1/12/18. Findings: Review of quality control (QC) documentation on the Abbott Diagnostic Cell Dyn 1800 showed that the laboratory failed to run quality control samples for twelve days before testing patients (1/12/18, 10/27/17, 9/20/17, 6 /21/17, 4/14/17, 3/24/17, 3/17/17, 3/10/17, 3/3/17, 2/10/17, 2/3/17, and 1/20/17). QC documentation also showed that a background check was not performed before testing patients on 9 out of the 10 days where QC was not performed (1/12/18, 10/27/17, 9/20 /17, 6/21/17, 4/14/17, 3/24/17, 3/17/17, 3/10/17, 3/3/17, 2/10/17, and 2/3/17). The Cell Dyn 1800 System Operator's Manual in section titled "Performing Daily Quality Control" states "On a daily basis, before running patients specimens, perform Quality Control (QC) procedure according to your laboratory's protocol." The operations manual also read, "When Background Counts and Quality Control are acceptable, patient specimens can be analyzed." Review of the laboratory's procedure manual in section 3.7 Quality Control states "Three (3) levels of commercially available whole blood quantitative controls are performed on a daily bases prior to performing analysis on patient specimens." During an interview on 1/15/19 at 2:30 AM, Clinical Consultant B acknowledged that the controls were not run.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to provide documentation of the Abbott Diagnostic Cell Dyn 1800 hematology analyzer's calibration performed at least every 6 months from 7/27/17 though 6/8/18. Findings: Review of the available calibration documentation for the hematology analyzer showed that there was no documentation of calibration performed between 7/27/17 and 6/8/18. During an interview on 1/15/19 at 3:05 PM, Clinical Consultant B stated that calibration was performed in January of 2018 but was unable to find the documentation.