

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D1019011	<b>(X3) Date Survey Completed</b>  10/22/2019
<b>Name of Provider or Supplier</b>  South Florida Center For Gynecologic Oncology	<b>Street Address, City, State</b>  6200 N Federal Hwy, Boca Raton, FL	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	A recertification survey was conducted on October 22, 2019. South Florida Center for Gynecologic Oncology clinical laboratory was found not in compliance with 42 CFR 493, requirements for clinical laboratories.
<b>D2007</b>	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>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</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to have all testing personnel rotate through the testing of proficiency testing samples for 2017 (3rd event), 2018 (1st, 2nd and 3rd event), and 2019 (1st and 2nd event). Findings: Review of the American Proficiency Institute (API) proficiency testing attestation forms showed that Testing Personnel B performed all the Proficiency Testing (PT) for 2018 (1st, 2nd and 3rd event), and 2019 (1st and 2nd event). Review of the CMS-209 form title "Laboratory Personnel Report (CLIA)" that was signed and dated by the Laboratory Director on 10/9/19 listed 2 testing personnel. During an interview on 10/22/19 at 11:33 AM, the Manager A acknowledged that Testing Personnel B performed all the proficiency testing for the laboratory in 2018 and 2019, and that Testing Personnel B had performed the PT for the 3rd event in 2017 and failed to sign the attestation.</p>
<b>D2122</b>	<p>HEMATOLOGY CFR(s): 493.851(b)</p> <p>Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.</p>

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 second testing event of 2019 for the specialty of Hematology. Findings: Review of the PT Performance Summary from American Proficiency Institute (API) for the second event of 2019 showed unsatisfactory scores for the CMS (Center for Medicare & Medicaid Services) reportable analytes of Erythrocyte count 60%, Hematocrit 60%, Hemoglobin 60%, Leukocyte Count 60%, Platelet Count 60%, and White Blood Cell Differential 60%. The overall score for the specialty of hematology was 60% (Erythrocyte count 60% + Hematocrit 60% + Hemoglobin 60% + Leukocyte Count 60% + Platelet Count 60% + White Blood Cell Differential 60% = 360% divided by 6 analytes = 60%). During an interview on 10/22 /19 at 11:25 AM, the Manager confirmed the laboratory had an unsuccessful scores in proficiency testing for the second event in 2019.

**D5200**

**GENERAL LABORATORY SYSTEMS**  
 CFR(s): 493.1230

Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed.

This CONDITION is not met as evidenced by:  
 Based on record review and interview, the laboratory's quality assessment program failed to monitor and evaluate the overall quality of the general laboratory system and correct problems identified. Findings: Cross Reference D5209. Based on record review and staff interview, the laboratory failed to document competency assessment on 1 (B) of 2 Testing Personnel for 2018. Cross Reference D5221. Based on record review and interview, the laboratory failed to document proficiency testing (PT) evaluation and verification activities.

**D5209**

**PERSONNEL COMPETENCY ASSESSMENT POLICIES**  
 CFR(s): 493.1235

As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.

This STANDARD is not met as evidenced by:  
 Based on record review and staff interview, the laboratory failed to document competency assessment on 1 (B) of 2 (A, B) Testing Personnel for 2018. Findings: Review of the annual competency records showed that the laboratory failed to have documentation of competency assessment on Testing Personnel B for 2018. During an interview on 10/22/19 at 11:52 AM, the Manager stated she was unable to locate the competency assessment on Testing Personnel B for 2018..

**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 record review and interview, the laboratory failed to document proficiency testing (PT) evaluation and verification activities. Findings: 1. Review of the API, "Proficiency Testing Performance Evaluation" form showed that the laboratory director failed to document corrective action take for unacceptable results for the 2018 3rd event (60% granulocytes, 80% monocytes), the 2019 1st event (80% lymphocytes), and 2019 2nd event (60% hematology). The API "Proficiency Testing Performance Evaluation" form stated, "Laboratories should review the Performance Summary and Comparative Evaluation thoroughly for failures or 'not graded' analytes. Laboratories are responsible for documenting and performing corrective action for failures". During an interview on 10/22/19 at 11:30 AM, the Manager acknowledged that no corrective action was documented. 2. Review of the American Proficiency Institute (API) PT records showed that the laboratory failed to verify that PT samples were run in the same manner as patients by signing the attestation statement. Attestation statements for the 2017 hematology 3rd event was not signed by Testing Personnel B or the Laboratory Director. The API attestation statement stated, "Signature Required - Testing Personnel and the Laboratory Director must physically sign an attestation statement for all PT results." During an interview on 10/22/19 at 11:33 AM, the Manager A acknowledged that Testing Personnel B performed the proficiency testing for the 3rd event in 2017 and that the attestation was not signed by the Testing Personnel B or the Laboratory Director.

**D5400**

**ANALYTIC SYSTEMS**

CFR(s): 493.1250

Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.

This CONDITION is not met as evidenced by:

Based on record review and interview, the laboratory's quality assessment program failed to monitor and evaluate the overall quality of the analytic system and correct identified problems. Findings: Cross Reference D5403. Based on record review and interview, the laboratory's written procedure manual was incomplete. Cross Reference D5481. Based on record review and interview, the laboratory failed to provide all the quality control (QC) documentation on the Beckman Coulter Act Diff 2 hematology analyzer. Cross Reference D5547. Based on record review and interview, the laboratory failed to have a reagent log that listed when the reagents for the Beckman Coulter Act Diff 2 were used from 10/22/17 to 10/22/19.

**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 record review and interview, the laboratory's written procedure manual was incomplete. Findings: Review of the laboratory's procedure manual, signed by the Laboratory Director on 3/17/19, showed the procedure manual did not include a procedure on normal values, alert (critical) values and proficiency testing (PT). During an interview on 10/22/19 at 1:01 PM, the Manager acknowledged that she was unable to locate procedures on normal values, values, critical values, and proficiency testing (PT).

**D5481**

**CONTROL PROCEDURES**

CFR(s): 493.1256(f)(g)

(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory failed to provide all the quality control (QC) documentation on the Beckman Coulter Act Diff 2 hematology analyzer. Findings: 1. Review of the laboratory's records revealed that the background checks and daily QC (low, normal and high controls) records were missing from 10/22/17 to 12/31/17. During an interview on 10/22/19 at 12:00 PM, the Manager stated she did not know where the background check and daily QC results for 2017 were located. 2. Review of QC records for July and December 2018, and May 2019 showed that for each day a background check was performed, there were no records of the daily QC (low, normal and high controls) for 24 out of 58 days. Background checks were performed in 2018 on July 2, 3, 5, 6, 9, 10, 11, 12, 13, 16, 17, 18, 19, 20, 23, 24, 25, 26, 27, 30, and 31. No daily QC was found in 2018 for July 6, 11, 13, 17, 19, 24, and 26. Background checks were performed in 2018 on December 3, 4, 5, 6, 7, 10, 11, 12, 13, 14, 18, 19, 21, 26, 27, 28, and 31. No daily QC was found in 2018 for December 6, 11, 13, 14, 19, 21, 26, and 28. Background checks were performed in 2019 on May 1, 2, 3, 7, 8, 10, 13, 14, 15, 16, 17, 20, 21, 22, 23, 24, 28, 29, 30, and 31. No daily QC

was found in 2019 for May 1, 7, 10, 14, 17, 20, 22, 24, and 30. During an interview on 10/22/19 at 12:39 PM, the Manager did not know where the daily QC results for the missing days were located.

**D5547**

**HEMATOLOGY**  
CFR(s): 493.1269(c)(d)

(c) For manual coagulation tests-- (c)(1) Each individual performing tests must test two levels of control materials before testing patient samples and each time a reagent is changed; and (c)(2) Patient specimens and control materials must be tested in duplicate. (d) The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:  
Based on record review and interview, the laboratory failed to have a reagent log that listed when the reagents for the Beckman Coulter Act Diff 2 were used from 10/22/17 to 10/22/19. Findings: Review of the quality control documentation showed that the laboratory did not have any records indication when the reagents for the hematology analyzer were opened. During an interview on 10/22/19 at 12:31 PM, the Manager acknowledged that they were not recording the open dates on a reagent log or the package inserts.

**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 record review and interview, the Laboratory Director failed to provide overall management and direction. Findings: Cross Reference D6004. Based on record review and Interview, the Laboratory Director failed to ensure that Testing Personnel B was competent in 2018. Cross Reference D6007. Based on record review and interview, and record review, the Laboratory Director failed to ensure that testing systems used in the laboratory provided quality laboratory services for all aspects of testing performance, including analytic phases of testing from 10/22/17 to 10/22/19. Cross Reference D6018. Based on record review and interview, the Laboratory Directory failed to evaluate the laboratory's performance of proficiency testing (PT) and identify problems in proficiency testing that required corrective action.

**D6004**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(a)(b)

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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If

the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:

Based on record review and interview, the Laboratory Director failed to ensure that Testing Personnel B was competent in 2018. Findings: Based on record review and staff interview, the laboratory failed to document competency assessment on 1 (B) of 2 Testing Personnel for 2018. (See D5209)

**D6007**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(1)

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)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing;

This STANDARD is not met as evidenced by:

Based on record review and interview, the Laboratory Director failed to ensure that testing systems used in the laboratory provided quality laboratory services for all aspects of testing performance, including analytic phases of testing from 10/22/17 to 10/22/19. Findings: Based on record review and interview, the Laboratory Director failed to identify that the laboratory's written procedure manual was incomplete. (See D5403) Based on record review and interview, the Laboratory Director failed to ensure that the laboratory provide all the quality control (QC) documentation on the Beckman Coulter Act Diff 2 hematology analyzer. (See D5481) Based on record review and interview, the Laboratory Director failed to ensure that the laboratory have a reagent log that listed when the reagents for the Beckman Coulter Act Diff 2 were used from 10/22/17 to 10/22/19. (See D5547)

**D6018**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(4)(iii)

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)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;

This STANDARD is not met as evidenced by:

Based on record review and interview, the Laboratory Directory failed to evaluate the laboratory's performance of proficiency testing (PT) and identify problems in proficiency testing that required corrective action. Findings: Based on record review and interview, the Laboratory Director failed to ensure that all testing personnel rotate

through the testing of proficiency testing samples for 2017 (3rd event), 2018 (1st, 2nd and 3rd event), and 2019 (1st and 2nd event). (See D2007) Based on record review and interview, the Laboratory Director failed to ensure the laboratory receive a passing proficiency test (PT) score for the second testing event of 2019 for the specialty of Hematology. (See D2122) Based on record review and interview, the Laboratory Director failed to ensure that the laboratory documented proficiency testing (PT) evaluation and verification activities. (See 5221)