| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 10D1019011 | 10/21/2021 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| South Florida Center For Gynecologic Oncology | 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.

| (X4) ID Prefix Tag | Summary Statement of Deficiencies |
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| **D0000** | A recertification survey conducted on 10/15/2021-10/21/2021, found South Florida Center For Gynecologic Oncology clinical laboratory not in compliance with 42 CFR Part 493, Requirements for Laboratories. |
| **D5439** | CALIBRATION AND CALIBRATION VERIFICATION<br>CFR(s): 493.1255(b)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and interview, the laboratory failed manufacture's instructions to do six-month calibration in 2021 for the Medonic-M Series instrument in |

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| | Hematology. Findings included: Review of Medonic-M Series calibration folder revealed no documentation of completing a six-month calibration in 2021 for Medonic-M Series instrument. Review of Medonic M-Series calibration maintenance revealed calibrations are a 6-month maintenance requirement for the Medonic-M Series. During an interview on 10/21/2021 at 11:06AM, the office manager confirmed the six-month calibration was not performed in 2021 on Medonic-M Series. |