

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D2140787	<b>(X3) Date Survey Completed</b>  07/02/2019
<b>Name of Provider or Supplier</b>  Wellingtonmd Llc	<b>Street Address, City, State</b>  12989 Southern Blvd Building 3 Ste 103, Loxahatchee, 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>	An announced CLIA recertification surey was conducted at Wellington MD on 07/02 /2019. The laboratory was not in compliance with 42 Code of Federal Regulations (CFR), Part 493, requirements for laboratories.
<b>D5439</b>	<p><b>CALIBRATION AND CALIBRATION VERIFICATION</b> CFR(s): 493.1255(b)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with laboratory personnel, the laboratory did</p>

not perform calibration verification every six months for prostate specific antigen (PSA) testing. Findings include: Review of calibration records for PSA testing on 07/02/2019 revealed that the laboratory did a two point calibration. During an interview with the laboratory director at 10:45 a.m. on 07/02/2019 he confirmed that they did a two point calibration for PSA's and they did not do calibration verifications every six months as it specified in their procedure manual.

**D6053**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:  
Based on record review and interview with laboratory personnel, there was no documentation to indicate that the technical consultant documented semiannual competency for the moderate complexity testing testing person. Findings include: Review of training records on 07/02/2019 for the one testing person revealed that she started training in July, 2018. During an interview with the laboratory director at 10:45 a.m. on 07/02/2019, he confirmed that there was no documentation of a semiannual competency review of her.