

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 10D2140787	<b>(X3) Date Survey Completed</b> 12/02/2025
<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 survey was conducted at Wellington LLC on December 2, 2025. The laboratory was surveyed under 42 CFR Part 493 CLIA requirements. Standard deficiencies were cited are as follows:
<b>D2007</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> CFR(s): 493.801(b)(1)</p> <p>(b)(1) 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 performing proficiency testing (PT) for the specialties of Chemistry for seven of seven (2023 3rd, 2024 1st, 2nd, 3rd, and 2025 1st, 2nd, 3rd) events. Findings: 1. Review of the Laboratory Personnel Report, signed and dated by the Laboratory Director on 12/01//2025, listed two testing personnel. 2. Review of the procedure titled, Proficiency Testing noted, "Testing of proficiency samples should be rotated among all laboratory staff performing patient testing." 3. Review of the proficiency testing records from American Proficiency Institute PT showed all the PT event were performed by the Laboratory Director (Testing Personnel A). 4. On 12/02 /2025 at 3:23 PM, the Laboratory Director stated he ran all the PT samples.</p>
<b>D5781</b>	<p><b>CORRECTIVE ACTIONS</b> CFR(s): 493.1282(b)(1)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b),</p>

which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

Based on observation, record review and interview, the laboratory failed to identify and document corrective actions for temperatures out of range for the refrigerator for 16 days of operation from 06/07/2023 to 12/02/2025. Findings: 1. A tour of the laboratory on 12/02/2025 at 1:20 PM, revealed chemistry reagents were stored in the laboratory refrigerator. 2. Review of the boxes and package insert for reagents in the laboratory refrigerator showed the reagents had a storage temperature of 2 - 8 degrees Celsius (C). The following reagents were located in the refrigerator: AIA-Pack PA (prostate antigen) Calibration Set, AIA-Pack PA Calibration Verification Test Set, AIA-Pack E2 (estradiol) Calibration Set, AIA-Pack E2 Calibration Set, Bio-Rad Liquichek Immunoassay Plus Control Level 1 and 3, ST AIA-Pack Testosterone, ST AIA-Pack PA, ST AIA-Pack E2, and ST AIA-Pack Testosterone. 3. Review of the laboratory temperature chart showed the temperatures were below 2 degrees C for the laboratory refrigerator with no correction action documented for the following 16 days: 01/27/2024 recorded 1.2 degrees C 01/30/2024 recorded 1.3 degrees C 02/09/2024 recorded 1.1 degrees C 02/24/2024 recorded 1.0 degrees C 05/22/2025 recorded 0.1 degrees C 05/29/2024 recorded 1.1 degrees C 05/30/2024 recorded 1.9 degrees C 08/03/2024 recorded 1.6 degrees C 08/08/2024 recorded 1.3 degrees C 09/11/2024 recorded 1.5 degrees C 09/14/2024 recorded 1.6 degrees C 09/18/2024 recorded 1.9 degrees C 09/20/2024 recorded 1.2 degrees C 09/21/2025 recorded -0.7 degrees C 09/26/2024 recorded 1.2 degrees C 10/02/2024 recorded 1.5 degrees C 4. Review of the procedure titled General Maintenance noted, "Record Temperatures on a daily basis. If the temperature is outside the acceptable range, note on the daily temperature log. Complete the following corrective actions: a. Check for the source of the problem . . . b. Adjust the thermostat, if necessary c. Check temperature at a later time during the same day . . . ." 5. Review of the Corrective Action log showed there was no corrective action documented for the days the refrigerator temperatures were out of range. 6. On 12/02/2025 at 3:15 PM, the Laboratory Director acknowledged the temperatures were out of range and corrective action taken was not documented.