

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D2078217	<b>(X3) Date Survey Completed</b>  06/07/2018
<b>Name of Provider or Supplier</b>  Palm Beach Thyroid And Endocrinology Wellness Llc	<b>Street Address, City, State</b>  12957 Palms West Dr Ste 204, 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>D2015</b>	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with laboratory personnel, the director had not signed the attestation statements for the past two years of proficiency testing. Findings include: Review of two years of proficiency testing records for hematology, routine chemistry, and endocrinology on 06/07/18 revealed that all of the attestation statements were signed by the testing person but not by the laboratory director. During an interview with the testing person at 1:30 p.m. on 06/07/18, she confirmed that the attestation statements had not been signed by the director.</p>
<b>D5439</b>	<p>CALIBRATION AND CALIBRATION VERIFICATION 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;</p>

(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 with laboratory personnel, the laboratory did not calibrate the cell counter every six months. Findings include: Review of the standard operating procedures for the laboratory on 06/07/18 revealed that the laboratory's criteria for calibrating the cell counter was at least every six months. According to the calibration records, the cell counter had been calibrated on 06/02/16 and 08/24/17. During an interview with the testing person at 1:15 p.m. on 06/07/18, she confirmed that the cell counter had not been calibrated every six months.

**D6019**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(4)(iv)

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)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory.

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 director ensured that corrective action was performed when proficiency testing results were unsatisfactory. Findings include: Review of proficiency testing records for the past two years on 06/07/18 revealed that for the first testing event of 2017, the laboratory received an unsatisfactory overall score of 78% for hematology, and for the third testing event of 2016 they received an unsatisfactory score of 60% for platelet count. During an interview with the testing person at 1:20 p.m. on 06/07/18, she confirmed that there was no documentation to indicate that any corrective action had been taken.

**D6046**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of

all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

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 testing person had competency evaluations performed. Findings include: Review of standard operating procedures on 06/07/18 revealed that testing personnel should be evaluated annually. There were no competency evaluations with the testing person's training information, and during an interview with her at 1:10 p.m. on 06/07/18 she said that she had been there almost two years and did not have documented competency evaluations.