

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0908796	(X3) Date Survey Completed 11/07/2019
Name of Provider or Supplier Alan L Tannenbaum Md Pa	Street Address, City, State 523 Cape Coral Pkwy E, Cape Coral, 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
D0000	An announced recertification survey was conducted on 11/7/19 at Alan L. Tannenbaum, M.D. PA, a clinical laboratory in Cape Coral, Florida. Alan L. Tannenbaum, M.D. PA was not in compliance with Code of Federal Regulations (CFR), Part 493, requirements for clinical laboratories. The following is a description of the non-compliance.
D2098	<p>ENDOCRINOLOGY CFR(s): 493.843(a)</p> <p>Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with laboratory personnel, the laboratory did not get at least 80 percent for each analyte in two testing events over the past two years. The findings included: Review of proficiency testing records for the past two years on 11/7/19 revealed that the laboratory received a score of 0 percent for thyroxine on the third testing event of 2018, and 0 percent for free thyroxine, thyroid-stimulating hormone (TSH), and thyroxine on the third testing event of 2019. During an interview with the testing person at 10:20 a.m. on 11/7/19, she confirmed that they had received some unacceptable scores in endocrinology.</p>
D2105	<p>ENDOCRINOLOGY CFR(s): 493.843(e)</p> <p>(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be</p>

maintained by the laboratory for two years from the date of participation in the proficiency testing event.

This STANDARD is not met as evidenced by:

Based on record review and interview with laboratory personnel, there was no documentation of remedial action taken when the laboratory received unacceptable scores in an endocrinology proficiency testing event. The findings included: Review of proficiency testing records on 11/7/19 revealed that the laboratory received unacceptable score in free thyroxine, thyroid-stimulating hormone, and thyroxine for the third testing event of 2019 and that there was no documentation of remedial action. During an interview with the testing person at 10:20 a.m. on 11/7/19 she said that the problem was a calculation error and confirmed that there was no documentation of what happened or of remedial action taken.

D5439

CALIBRATION AND CALIBRATION VERIFICATION

CFR(s): 493.1255(b)

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.

This STANDARD is not met as evidenced by:

Based on record review and interview with laboratory personnel, the laboratory did not do calibrations on the cell counter every six months as their procedure manual specified. The findings included: Review of procedures for maintenance of the cell counter revealed that calibrations should be done every six months. Review of calibration records showed that calibrations were performed 6/20/19, 7/02/18, and 6/22/17. During an interview with the testing person at 10:50 a.m. on 11/7/19, she confirmed that there was no documentation to indicate that the instrument had 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, the laboratory director did not ensure that corrective action was followed when proficiency testing results were unacceptable. The findings included: Review of proficiency testing records on 11/7/19 revealed that the laboratory received unacceptable score in free thyroxine, thyroid-stimulating hormone, and thyroxine for the third testing event of 2019 and that there was no documentation of remedial action. During an interview with the testing person at 10:20 a.m. on 11/7/19 she said that the problem was a calculation error and confirmed that there was no documentation of what happened or of remedial action taken.

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 lack of documentation and interview with laboratory personnel, the technical consultant did not document a semiannual competency for one of one testing person. The findings included: There was no documentation of a competency evaluation in the testing person's personnel binder. During an interview with the testing person at 10:30 a.m. on 11/7/19, she said that she started working there in January of 2019 and that the technical consultant had not done a six-month evaluation.