

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0679211	(X3) Date Survey Completed 04/11/2019
Name of Provider or Supplier Therafirst Medical Center	Street Address, City, State 4011 N Federal Hwy, Fort Lauderdale, 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
D2015	<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, the laboratory failed to sign copies of attestation statements for 2017 (events 2 and 3), 2018 (events 1, 2, and 3) and 2019 (event 1). Findings include: Review of the laboratory's proficiency testing with American Association of Bioanalysts (AAB) showed that the laboratory director and testing personnel had not signed the attestation forms for 2017 (events 2 and 3), 2018 (events 1, 2, and 3) and 2019 (event 1). During an interview on 4/11/19 at 9:40 AM, Testing Personnel A acknowledged that the forms were not signed.</p>
D5211	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p>

This STANDARD is not met as evidenced by:
Based on record review and interview, the Laboratory Director failed to document the review and evaluation of proficiency testing for 2017 (events 2 and 3), and 2018 (events 1, 2, and 3). Findings: Review of the laboratory's proficiency testing with American Association of Bioanalysts (AAB) showed that the laboratory director not signed the results forms for 2017 (events 2 and 3), and 2018 (events 1, 2, and 3). During an interview on 4/11/19 at 9:40 AM, Testing Personnel A acknowledged that the forms were not signed.

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, the laboratory failed to provide a competency evaluation for 1 out of 1 testing personnel (A) for 2018. Findings: Review of employee competency record revealed that the competency evaluation on Testing Personnel A for 2018 was missing . During an interview on 4/11/19 at 10:23 AM, Testing Personnel A acknowledged that she was unable to find her 2018 competency evaluation.