

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 03D2122615	(X3) Date Survey Completed 12/17/2019
Name of Provider or Supplier Beacon Biomedical Inc	Street Address, City, State 275 N Gateway Dr Ste 145, Phoenix, AZ	
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
D5407	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedure manual and interview with the facility personnel, the laboratory failed to have the current laboratory director approve, sign and date test procedures before use. Findings include: 1. The current laboratory director indicated in the CLIA Federal Database and assigned on the CMS-209, Laboratory Personnel Form presented for review during the survey has been listed as laboratory director since 11/16/2018. 2. The policy and procedure manual presented for review during the survey conducted on December 17, 2019 was not approved, signed and dated by the current laboratory director. 3. The facility personnel confirmed that the policy and procedure manual indicated above was not approved, signed and dated by the current laboratory director.</p>
D5435	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2)</p> <p>For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.</p>

This STANDARD is not met as evidenced by:
Based on lack of policies presented for review and interview with the facility personnel, the laboratory failed to establish a policy in regards to monitoring the rpm's and timer of the incubating microplate shakers used in the test process. Findings include: 1. The laboratory performs patient testing in the specialty of Chemistry with an approximate annual test volume of 420. 2. The laboratory utilizes two separate incubating microplate shakers (serial #160913301 and serial #170619005) as part of the procedural steps for the CEA test and the Cripto test. The CEA test includes a procedural step to shake the specimen for 5 minutes at 300 rpm, while the Cripto test requires shaking the specimen for 5 minutes at 250 rpm. 3. No policy was presented for review to indicate the laboratory had a system in place to monitor the timing and speed of each incubating microplate shaker, including the frequency in which they are monitored. 4. The facility personnel acknowledged that there was no documented policy or procedure for monitoring the function of the incubating microplate shakers.

D6127

TECHNICAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1451(b)(9)

The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high 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 of a semi-annual competency evaluation for two testing personnel and interview with the facility personnel, the technical supervisor failed to evaluate and document the performance of individuals responsible for high complexity testing at least semiannually during the first year the individuals tested patient specimens. Findings include: 1. No semi-annual competency evaluation documentation was presented for review for two out of two testing personnel who began patient testing in 2018. 2. The laboratory's established policy titled '9.4. Competency Assessment' states, "Competency Assessment is performed twice in a Lab Personnel's first year and annually thereafter." 3. The facility personnel confirmed that the laboratory failed to have documentation of a semi-annual competency evaluation for the two testing personnel indicated above.