

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D2082408	(X3) Date Survey Completed 03/14/2019
Name of Provider or Supplier Moleculera Biosciences, Inc	Street Address, City, State 755 Research Parkway, Suite 448, Oklahoma City, OK	
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	The validation survey was performed on 03/14/19. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the president/chief executive officer, laboratory director, clinical laboratory supervisor /technical lead and operations manager during an exit conference performed at the conclusion of the survey.
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the clinical laboratory supervisor/technical lead, the laboratory failed to follow the manufacturer's instructions for performing maintenance procedures. Findings include: (1) At the beginning of the survey, the clinical laboratory supervisor/technical lead stated to the surveyors the BioTek Epoch and Eon Reader (washer #1 and washer #2) were used to perform Anti-Dopamine 1 Receptor Antibody, Anti-Dopamine 2 Receptor Antibody, Anti-Lysoganglioside GM1, and Anti-Tubulin testing. (2) Later during the survey, surveyor #2 reviewed the manufacturer's maintenance requirements as stated on the maintenance log. The requirements were as follows: (a) Weekly Maintenance (b) Monthly Absorbance Test Plate (c) 6-Month Liquid Test (3) Surveyor #2 then reviewed maintenance records from January 2017 through December 2018. The following was identified: (a) Weekly - Washer #1: (i) Not performed between 01/06/17 and 01/20/17 (ii) Not performed between 09/28/18 and 10/10/18 (iii) Not performed between 11/21/18 and 12/07/18 (b) Weekly - Washer #2 (i) Not performed between 01/06/17 and 01/20/17 (ii) Not performed between 08/25</p>

/17 and 09/08/17 (iii) Not performed between 09/28/18 and 10/10/18 (iv) Not performed between 11/21/18 and 12/07/18 (c) Monthly - Washer #1 (i) Not performed between 11/29/17 and 01/02/18 (d) Monthly - Washer #2 (i) Not performed between 11/29/17 and 01/02/18 (e) 6-Month Liquid Test - Washer #1 (i) Not performed between 02/28/18 and 11/28/18 (f) 6-Month Liquid Test - Washer #1 (i) Not performed between 02/28/18 and 11/28/18 (4) Surveyor #2 reviewed the records with the clinical laboratory supervisor/technical lead, who stated the above maintenance procedures had not been documented as being performed as required.

D5437

CALIBRATION AND CALIBRATION VERIFICATION
CFR(s): 493.1255(a)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b) (3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.

This STANDARD is not met as evidenced by:
Based on a review of manufacturer's instructions and interview with the clinical laboratory supervisor/technical lead, the laboratory failed to follow the manufacturer's instructions for performing calibrations. Findings include: (1) During the survey, the clinical laboratory supervisor/technical lead stated to the surveyors the Scintillation counter was used for counting the level of radioactivity in radioactively-tagged samples for the CaM Kinase II Assay; (2) Surveyor #1 reviewed the manufacturer's instructions for the Scintillation Counter. Section 2.7.2 of the operating manual under the heading "When Calibration Should Be Done" stated: (a) "The instrument should be calibrated daily for the first week or two after installation, until the phototubes settle in. After this initial warmup period, calibration can be performed as follows: Once a month. Prior to initiating dpm programs (recommended). When setting up a new isotope automatically using the New Isotope Setup program (required). Prior to setting up quench curves (required). Prior to initiating an Auto DPM program. Refer to Section 3.4.1 for information on Auto DPM Calibration (recommended)." (3) Surveyor #1 asked the technical supervisor if calibrations had been performed on the Scintillation Counter as recommended by the manufacturer above during the review period of 2018 and to date in 2019. The technical supervisor stated to the surveyor calibrations were not performed on the Scintillation Counter.