

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D2093699	(X3) Date Survey Completed 01/31/2018
Name of Provider or Supplier Awc Lab Services, Llc	Street Address, City, State 150 Cora Drive, Suite B, Baton Rouge, LA	
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	A Validation Survey was conducted on January 31, 2018 at AWC Lab Services, LLC, CLIA ID # 19D2093699. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D5449	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the laboratory failed to perform external positive and negative controls for each each day of testing for BioFire testing for eleven (11) of twelve (12) patients tested. Findings: 1. Observation by surveyor during the laboratory tour on January 31, 2018 revealed the laboratory utilized a Bio Fire Film Array instrument for Respiratory and Gastrointestinal (GI) Panel testing. 2. Review of the laboratory's quality control policy revealed the laboratory is to perform external quality control for each new lot or shipment or monthly. 3. Review of quality control records revealed the laboratory followed this policy. 4. Further review of laboratory records revealed no Individualized Quality Control Policy (IQCP) to support the reduction of quality control frequency from each day of patient testing to monthly or new lot and shipment. 5. Review of all patient test records for the BioFire revealed the following patient were testing without external quality control the day of patient testing: Patients 1-11 6. Interview with Personnel 1 confirmed the laboratory followed the</p>

manufacturer's instructions for quality control frequency but had not performed and IQCP study to reduce the frequency of quality control. Personnel 1 confirmed external quality control was not performed each day of patient testing.

D6020

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(5)

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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:
Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure that the quality control was maintained to assure quality laboratory services were provided. Refer to D5449.