Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2121293	02/12/2020
Name of Provider or Supplier	**Street Address, City, State**	
Arbor Diagnostics, Inc	1801 Royal Lane Suite 805, Dallas, TX	

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
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: ********** An unannounced revisit was performed on 2/11/20-2/12/20. New findings. Based on review of the laboratory policy, laboratory record review and staff interview the laboratory failed to check each batch of 8 of 8 media (Lim Broth, Blood Agar, Chocolate Agar, Columbia CNA Agar, Thayer Martin Agar, Macconkey Agar, Sabouraud Dextrose Agar, and Fluid Thioglycollate Medium) for sterility, its ability to support growth and, as appropriate, select or inhibit specific organisms from 2018 - 2019. Findings were: 1. Review of the laboratory policy CAP Exempt Media revealed "an individualized quality control plan (IQCP) was implemented by the laboratory director for media utilized in this laboratory that are listed as exempt from testing (CLSI-M22-A3) and require only visual examination and documentation for the following: breakage, contamination appearance and evidence of freezing or overheating for each shipment of purchase. Procedure for Exempt Media Verify delivery of the ordered amount. Check each medium type for multiple lot number or impending expiration dates. Report any expiration dates less than 4 weeks to the supervisor. Report any recurring problems to the manufacturer or distributor. Record the amount of media received, lot number, expiration date, and the arrival date for each type of media in the the Media QC log book. Label sleeves with the received date. Store media as specified by the

	manufacturer (usually 2-8 C) Perform visual inspection.. If media QC is satisfactory, document the results on the Media QC log. Print out for each lot the certificate of quality from the manufacturer's website for records of media control." 2. Review of the above policy revealed no procedure to verify the media's sterility, its ability to support growth and, as appropriate, select or inhibit specific organisms. 3. Review of the IQCP and media logs records from 2018 - 2019 revealed the laboratory failed to check each batch of BBL Lim Broth, Blood Agar, Chocolate Agar, Columbia CNA Agar, Thayer Martin Agar, Macconkey Agar, Sabouraud Dextrose Agar, Fluid Thioglycollate Medium for sterility, its ability to support growth and, as appropriate, select or inhibit specific organisms. 4. Random review of the media QC log revealed documentation the laboratory used the following lots of media with no documentation of the quality control for sterility, its ability to support growth and, as appropriate, select or inhibit specific organisms. McConkey lot 916342, exp 3/23/20 Blood lot 914992, exp 3/12/20 CNA lot 914996, exp 3/16/20 Chocolate lot 871737, exp 3/3/20 Jembec lot 906069, exp 2/11/20 Mueller Hinton lot 911267, exp 3/5/20 SAB Dex lot 904513, exp 3/2/20 Lim Broth lot 9276957, exp 7/14/20 Jembec lot 920219, exp 3/16 /20 CNA lot 909339, exp 2/27/20 McConkey lot 871732, exp 3/2/20 5. Review of the laboratory CMS116 revealed the laboratory performed ? microbiology tests annually. 6. Interview of the microbiology supervisor on 2/12/20 at 1305 hours in the conference room revealed that the facility was using Clinical and Laboratory Standards Institute (CLSI) guidance for quality control testing of media. She was unaware exempt media required quality control for sterility and the media's ability to support growth and, as appropriate, select or inhibit specific organisms key: IQCP - Individualized Quality Control Plan