Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	36D0341512	04/10/2018
Name of Provider or Supplier	**Street Address, City, State**	
Manor Ave Clinic Inc	296 E Manor Avenue, Struthers, OH	

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
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on record review and an interview with testing personnel (TP) #2, the laboratory failed to follow the manufacturer's reporting interpretation of throat culture results. Findings Include: 1. Review of the "BD BBL Taxo Discs for Differentiation of Group A Streptococci", provided on the date of the inspection, revealed the following statement: "Results A zone of inhibition is formed around the Taxo A disc if the organism is a group A streptococcus. It is recommended that any zone of inhibition, regardless of diameter, be reported as 'beta-hemolytic Streptococcus, presumptively group A by bacitracin.' No zone of inhibition...is reported as 'beta-

	hemolytic Streptococcus, presumptively not group A by bacitracin.'" 2. Review of four out of four of the laboratory's 2017 and 2018 patients who had a throat culture ordered, the "Throat Cultures" log sheets and final test report in the patient's paper chart revealed the following documentation: log sheet date log sheet result throat culture read and result reported 02/24/2017 +Pos Group A Strep 07/21/2017 -Neg Group A Strep 01/10/2018 -Neg Group A Strep 03/06/2018 -Neg Group A Strep 3. TP#2 confirmed the laboratory did not interpret and report throat culture results utilizing the Taxo A discs as indicated by the manufacturer's instructions. The interview occurred on 04/10/2018 at 3:39 PM.
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: Based on record review and an interview with testing personnel (TP) #2, the laboratory failed to check and document the ability of the Select Strep Agar (SSA) to select or inhibit organism growth and document the results of sterility testing for each lot number, each shipment received. Findings Include: 1. Review of the laboratory's "Quality Assurance Policies and Procedures" manual approved, signed and dated by the Laboratory Director on 05/02/2016, found instructions for SSA quality control (QC) procedures which included visual checks of the agar, sterility checks, the use of Streptococcus pyogenes and Streptococcus agalactiae to show that the SSA supports growth and produces (or not) a zone of inhibition around the Taxo A disc as appropriate, but did not find any mention of the use of an organism to show that the SSA would inhibit its' growth. 2. Review of the laboratory's 2016, 2017 and 2018 media QC records did not find the results of the sterility checks performed were documented. 3. TP#2 confirmed the laboratory did not include a QC organism to show that the SSA would inhibit its' growth and did not document the results of sterility checks for each lot number and each shipment of the SSA. The interview occurred on 04/10/2018 at 3 PM.